Bioethica

Vol 11, No 2 (2025)

Bioethica

Ελληνική Δημοκρατία
Εθνική Επιτροπή
Βιοηθικής & Τεχνοηθικής

ΙΝΣΤΙΤΟΥΤΟ ΠΛΗΡΟΦΟΡΙΚΗΣ & ΤΗΛΕΠΙΚΟΙΝΩΝΙΩΝ

2025 • Τόμος 11 • Τεύχος 2

2025 • Volume 11 • Issue 2

ΒΙΟΗΘΙΚΑ

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Ηλεκτρονικό Περιοδικό

Online Journal

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Το Περιοδικό "ΒΙΟΗΘΙΚΑ"

Το Περιοδικό "ΒΙΟΗΘΙΚΑ" αποτελεί ηλεκτρονική έκδοση της Εθνικής Επιτροπής Βιοηθικής & Τεχνοηθικής σε συνεργασία με το Ινστιτούτο Πληροφορικής και Τηλεπικοινωνιών του ΕΚΕΦΕ «Δημόκριτος». Τα θεματικά του ενδιαφέροντα καλύπτουν όλο το φάσμα της σύγχρονης βιοηθικής και τεχνοηθικής. Για τον λόγο αυτό, καλούμε όχι μόνο καθιερωμένους αλλά κυρίως νέους επιστήμονες να στείλουν τις συμβολές τους.

Σκοπός του Περιοδικού είναι η ενημέρωση και η ανταλλαγή απόψεων και γνώσεων μεταξύ των επιστημόνων όλων των κλάδων με ιδιαίτερο θεωρητικό ή πρακτικό ενδιαφέρον για θέματα που αφορούν στη Βιοηθική αλλά και τα ηθικά ζητήματα της τεχνολογίας. Για την επίτευξη αυτού του σκοπού, στο Περιοδικό δημοσιεύονται, στην ελληνική ή στις κύριες ευρωπαϊκές γλώσσες, εργασίες που αποτελούν Άρθρα Σύνταξης, Πρωτότυπες Εργασίες και Ανασκοπήσεις.

Οι Πρωτότυπες Εργασίες και οι Ανασκοπήσεις διαβιβάζονται ανώνυμα σε διεπιστημονική ομάδα κριτών, οι οποίοι τις αξιολογούν. Μόνο όσες εργασίες λάβουν οριστική έγκριση από τους κριτές δημοσιεύονται στο Περιοδικό. Επισημαίνεται ότι οι απόψεις στα κείμενα εκφράζουν μόνο τους συγγραφείς.

Αναλυτικές πληροφορίες για το Περιοδικό "ΒΙΟΗΘΙΚΑ" θα βρείτε στην ιστοσελίδα του Εθνικού Κέντρου Τεκμηρίωσης (ΠΕΡΙΟΔΙΚΟ Bioethica).

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Άρθρο Σύνταξης - Editorial

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Αναστοχασμοί για τις τεχνοηθικές και βιοηθικές στάσεις στην Ελλάδα

Χαράλαμπος Τσέκερης, Κωνσταντίνος Καρπούζης, Σταυρούλα Τσινόρεμα, Τάκης Βιδάλης

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Λέξεις κλειδιά: βιοηθική, τεχνοηθική, τεχνητή νοημοσύνη, ψηφιακός εγγραμματισμός, έλεγχος περιεχομένου, ευθανασία, παρένθετη κυοφόρος, επιλογή εμβρύου.

Reflections on technoethical and bioethical attitudes in Greece

Charalampos Tsekeris, Konstantinos Karpouzis, Stavroula Tsinorema, Takis Vidalis

Hellenic National Commission for Bioethics and Technoethics, Athens, Greece.

Keywords: bioethics, technoethics, artificial intelligence, digital literacy, fact-checking, euthanasia, surrogate mother, embryo selection.

Με τη διενέργεια της πρώτης πανελλαδικής εμπειρικής έρευνας σε θέματα που την απασχολούν, η Εθνική Επιτροπή Βιοηθικής και Τεχνοηθικής (ΕΕΒΤ) εγκαινιάζει μια πρακτική που θα αποτελέσει πολύτιμο οδηγό στην επεξεργασία των Γνωμών και Συστάσεών της. Τα ευρήματα από την πρώτη μας έρευνα αποτυπώνουν τις τρέχουσες στάσεις την ελληνικής κοινωνίας και είναι ασφαλώς ενδιαφέροντα. Για την Επιτροπή είναι ακόμη πιο σημαντικό το ότι με την πρωτοβουλία αυτή τέθηκαν στο ευρύ κοινό προβληματισμοί που συνήθως απασχολούν έναν περιορισμένο κύκλο ειδικών. Ωστόσο, η ηθική διάσταση των νέων τεχνολογιών είναι ανάγκη να μας ευαισθητοποιεί όλους. Στο πνεύμα αυτό, ακολουθούν κάποιες σκέψεις για την αποτίμηση των αποτελεσμάτων της έρευνας.

Τεχνοηθική

Οι απαντήσεις που περιλαμβάνονται στην έρευνα και αφορούν στον αντίκτυπο των τεχνολογιών του διαδικτύου κατά τα επόμενα χρόνια αναδεικνύουν τη διχοτόμηση των πολιτών σχετικά με τον ρόλο τους στο μέλλον: πάνω από 4 στους 10 απάντησαν ότι «θα έχει χειροτερέψει τον κόσμο», σχεδόν 3 στους 10 κράτησαν ουδέτερη στάση, λέγοντας ότι δεν θα έχει ούτε βελτιώσει ούτε χειροτερέψει την κατάσταση, με το υπόλοιπο ποσοστό να θεωρεί ότι το διαδίκτυο «θα έχει βελτιώσει τον κόσμο». Το εύρημα αυτό δείχνει πως, ενώ αναγνωρίζονται οι δυνατότητες του διαδικτύου, η πλειονότητα τείνει να βλέπει τις αρνητικές συνέπειες ως πιθανότερες και ισχυρότερες από τις θετικές χρήσεις του. Το ίδιο αποτυπώνεται και αναφορικά με το ζήτημα της αξιοπιστίας: στο ερώτημα αν πρέπει να υπάρχει θεσμοθετημένος έλεγχος της εγκυρότητας των πληροφοριών (fact-checking), σχεδόν 40% απάντησε αρνητικά, φοβούμενο τη λογοκρισία, με πάνω από τους μισούς πάντως να αναγνωρίζουν την παραπληροφόρηση ως ένα σημαντικό πρόβλημα που χρειάζεται αντιμετώπιση. Αυτό δείχνει ότι η κοινωνία αναγνωρίζει τον κίνδυνο της παραπληροφόρησης, αλλά ταυτόχρονα απορρίπτει λύσεις που μπορεί να περιορίσουν την ελευθερία του λόγου.

Σε ό,τι αφορά στις στάσεις απέναντι στην τεχνητή νοημοσύνη (ΤΝ), οι απαντήσεις δείχνουν ότι σχεδόν 80% εκτιμούν ότι θα υπονομεύσει τις ανθρώπινες σχέσεις μέχρι το 2040, με λιγότερο από 1 στους 10 να προσδοκά βελτίωση σε αυτόν τον τομέα. Αντίστοιχα, στο ερώτημα για τη δημοκρατία, περισσότεροι από 6 στους 10 πιστεύουν ότι η ΤΝ θα την υπονομεύσει, ενώ λιγότεροι από 1 στους 10 πιστεύουν ότι μπορεί να την ενισχύσει. Αυτά τα στοιχεία έχουν έμμεση σχέση και με την εκπαίδευση γύρω από τη χρήση και λειτουργία τέτοιων τεχνολογιών, καθώς αναδεικνύουν την ανάγκη για την καλλιέργεια δεξιοτήτων ψηφιακού γραμματισμού, κριτικής σκέψης και συνειδητοποίησης των ηθικών και κοινωνικών διαστάσεων της τεχνολογίας, ώστε οι πολίτες να μπορούν να συμμετέχουν ενεργά και υπεύθυνα σε μια κοινωνία που θα λειτουργεί με τη μεσολάβηση συστημάτων ΤΝ.

Όσον αφορά στα τεχνοηθικά διλήμματα στον προσωπικό ή τον επαγγελματικό χώρο, αυτά γίνονται πιο συγκεκριμένα μέσα από σενάρια που αφορούν στην οικιακή φροντίδα και την εργασία. Σε ερώτηση για το αν ένα ρομπότ με εξελιγμένη ΤΝ θα μπορούσε να φροντίζει ηλικιωμένους ή ασθενείς στο σπίτι, η απάντηση ήταν αρκετά σαφής, αφού το 73% βλέπει αρνητικά την προοπτική ενός τέτοιου σεναρίου, δείχνοντας ότι οι πολίτες απορρίπτουν την ιδέα η φροντίδα, που θεωρείται κατεξοχήν ανθρώπινη εργασία, να ανατεθεί σε μηχανές. Αντίστοιχα, το ερώτημα για το αν η ΤΝ θα μπορούσε να λειτουργεί χωρίς ανθρώπινη επιτήρηση είχε εξίσου σαφή απάντηση: πάνω από 8 στους 10 (86%) τάχθηκαν κατά, με 71% να δηλώνουν απόλυτα βέβαιοι για τη θέση τους. Μόνο το 13% εμφανίστηκε θετικό στην προοπτική αυτή, με το εύρημα να υποδηλώνει πως οι πολίτες θεωρούν την ανθρώπινη επίβλεψη απαραίτητη, ιδίως σε εργασιακά περιβάλλοντα όπου τα λάθη μπορεί να έχουν σημαντικές συνέπειες.

Συνολικά, ενώ ο ουσιαστικός αντίκτυπος από την ΤΝ στην καθημερινότητα και την εργασία μας είναι μάλλον νωρίς να αποτιμηθεί, είτε πρόκειται για τα οφέλη, είτε για τις πιθανές αρνητικές επιπτώσεις, τα αποτελέσματα της έρευνας καταδεικνύουν το ενδιαφέρον και την έντονη ανησυχία των πολιτών, πιθανώς και λόγω περιορισμένης ή επιφανειακής χρήσης της. Οι

πρόσφατες πρωτοβουλίες για το πιλοτικό πρόγραμμα χρήσης Μεγάλων Γλωσσικών Μοντέλων (LLMs) από εκπαιδευτικούς και μαθητές αναμένεται να αναδείξουν τις θετικές προοπτικές, όχι μόνο στο εκπαιδευτικό περιβάλλον αλλά και στην ερευνητική διαδικασία, τονίζοντας παράλληλα το πώς η ΤΝ μπορεί να περιορίσει τη διάθεση για κριτική σκέψη, να ενισχύσει πολιτισμικά ή έμφυλα στερεότυπα και να μειώσει τον χώρο για δημιουργική έκφραση, αν επιτρέψουμε να υποκαταστήσει τον ανθρώπινο παράγοντα. Κάποια από τα πιθανά σενάρια σχετικά με τη χρήση ΤΝ στο εκπαιδευτικό περιβάλλον περιγράφονται στην πρόσφατη γνώμη και έκθεση της ΕΕΒΤ και εξηγούν το πώς μπορούν να εξελιχθούν θετικά ή αρνητικά, ανάλογα με το πώς θα αξιοποιήσουμε τα εργαλεία, ποιες από τις εργασίες και ευθύνες θα τους εκχωρήσουμε, αλλά και τον βαθμό επίβλεψης από τους εκπαιδευτικούς, τους μαθητές ή τους γονείς.

Σε κάθε περίπτωση, καλό είναι να θυμόμαστε πώς η έλλειψη συγκεκριμένου θετικού ή αρνητικού προσήμου που να συνοδεύει εξ αρχής την ΤΝ σε καμιά περίπτωση δεν σημαίνει ότι είναι ουδέτερη. Η τεχνολογία, όπως το θέτει ο M. Kranzberg, δεν είναι μια «αντικειμενική δύναμη»· διαμορφώνεται από τους ανθρώπους που την σχεδιάζουν, την δημιουργούν και την εφαρμόζουν μέσα σε συγκεκριμένα ιστορικοκοινωνικά συμφραζόμενα. Είναι ένας σχεσιακός «καθρέφτης» (S. Vallor) για να κοιτάξουμε καλύτερα τις δικές μας, ανθρώπινες ηθικές και ηθικοκοινωνικές ευαλωτότητες και προκλήσεις, καθώς και τις νέες μορφολογίες εξουσίας (L. Floridi).

Πέρα από την ανάγνωση των ευρημάτων της έρευνας με μια προσέγγιση αισιοδοξίας/απαισιοδοξίας, αναδεικνύεται με σαφή τρόπο μια δημοκρατική εντολή για ανθρωποκεντρική λογοδοσία με αναλογικότητα: οι πολίτες αναγνωρίζουν τη ζημιά της παραπληροφόρησης, αλλά φοβούνται λύσεις που απειλούν ή υπονομεύουν την ελευθερία του λόγου (σημαντικό ποσοστό απορρίπτει το θεσμοθετημένο fact-checking), ενώ βλέπουν την ΤΝ ως απειλή για τις διαπροσωπικές σχέσεις και τη δημοκρατία (η πλειοψηφία προβλέπει υπονόμευση και στα δύο), ζητώντας ταυτόχρονα αδιαπραγμάτευτη ανθρώπινη επίβλεψη και απορρίπτοντας μηχανική υποκατάσταση στη φροντίδα (αρνητικές στάσεις για ρομποτική οικιακή φροντίδα, πολύ υψηλή απαίτηση για ανθρώπινη επιτήρηση).

Τα ευρήματα αυτά δεν προτείνουν "λευκές επιταγές" στην καινοτομία, ούτε γενικευμένη απαγόρευση, αλλά θεσμούς, διαδικασίες και ηθικές σχεδιαστικές επιλογές (ethics by design) που μειώνουν την πιθανότητα βλαβερών ή επιζήμιων συνεπειών, ενδυναμώνουν την πρακτική κρίση των χρηστών και διασφαλίζουν τη δυνατότητα αντίρρησης και επανόρθωσης. Με άλλα λόγια, η διαπίστωση ότι η τεχνολογία δεν είναι ουδέτερη (Kranzberg) γίνεται θετική δέσμευση για συμμετοχικό συν-σχεδιασμό, διαφάνεια και κυκλική αξιολόγηση επιπτώσεων με τη φωνή εκπαιδευτικών, γονέων και εργαζομένων στο επίκεντρο.

Βιοηθική

Το δεύτερο μέρος της έρευνας ανέδειξε στάσεις του κοινού για ορισμένα ζητήματα που απασχολούν από καιρό τη βιοηθική και έχουν προκαλέσει έντονες διχογνωμίες μεταξύ των ειδικών. Τα ζητήματα αυτά αφορούν στις αποφάσεις περί (ή για) το τέλος της ζωής (όπως τη διακοπή της τεχνητής υποστήριξης ζωτικών λειτουργιών, ή την "ευθανασία") και την υποβοηθούμενη αναπαραγωγή (όπως παρένθετη μητρότητα, επιλογή εμβρύου).

Αναφορικά με τις πρώτες, η πλειονότητα των απαντήσεων (61%) θα ήθελε οι προγενέστερες οδηγίες και οι διαθήκες ζωής (που μπορεί να περιλαμβάνουν αιτήματα «παθητικής» ή «ενεργητικής» ευθανασίας ή άρνησης θεραπευτικής παρέμβασης) να είναι δεσμευτικές για τους θεράποντες ιατρούς και τους οικείους ασθενών που δεν είναι σε θέση να εκφράσουν τη βούλησή τους. Αποχρώσεις στις απαντήσεις υπάρχουν, αλλά οι περισσότερες δέχονται η δεσμευτικότητα αυτή να είναι απόλυτη.

Ως προς τις συγκεκριμένες επιλογές για το τέλος της ζωής, ένα ποσοστό 60% δέχεται την διακοπή της τεχνητής υποστήριξης της ζωής όταν δεν υπάρχει πιθανότητα ανάρρωσης του ασθενούς («παθητική» ευθανασία). Εντυπωσιάζει η θετική στάση για την «ενεργητική» ευθανασία ενός ποσοστού 43%, η οποία συμπληρώνεται με ένα 28% που ζητά και τη σύμφωνη γνώμη των

συγγενών του ασθενούς, πέρα από τη δική του απόφαση. Μόνο 3 στους 10 διαφωνούν με την επιλογή αυτή (ή δεν έχουν άποψη).

Με βάση αυτά τα ευρήματα, το ελληνικό κοινό δείχνει να μη συμμερίζεται τη στάση της σημερινής νομοθεσίας που είτε παραμένει επιφυλακτική (προγενέστερες οδηγίες), είτε απαγορεύει τις επιλογές «παθητικής» και «ενεργητικής» ευθανασίας. Οι απαντήσεις δείχνουν μια σαφή προτίμηση στην προσωπική αυτονομία του ασθενούς, ακόμη και σε τόσο κρίσιμες ηθικά περιστάσεις.

Ως προς τα ζητήματα της υποβοηθούμενης αναπαραγωγής, ιδιαίτερο ενδιαφέρον παρουσιάζουν οι απαντήσεις για την παρένθετη μητρότητα. Σχεδόν ο ένας στους τρεις από όσους ερωτήθηκαν θεωρεί ότι η παρένθετη κυοφόρος πρέπει να έχει το δικαίωμα να κρατήσει το παιδί, παρά τη συμφωνία με το ζευγάρι που το επιθυμεί, αντίθετα με την σημερινή πρόβλεψη του νόμου. Είναι πιθανόν η απάντηση αυτή να αξιολογεί την εμπειρία της κυοφορίας ως τόσο καθοριστική για την ψυχοσύνθεση της παρένθετης κυοφόρου, ώστε να μη δικαιολογείται πάντοτε η τήρηση της συμφωνίας με το ζευγάρι. Ένα σημαντικό ποσοστό εξάλλου (45%) βλέπει την παρένθετη ως εργαζόμενη που πρέπει να αμείβεται και όχι να αρκείται σε μια αποζημίωση για τη συμβολή της στην τεκνοποιία. Η στάση αυτή δείχνει ότι η πρόθεση του νόμου να καθιερώσει τη μέθοδο στη βάση της αλληλεγγύης, δεν πείθει ιδιαίτερα το κοινό. Αυτό, μάλιστα, ακόμη και αν ο νόμος δέχεται αποζημίωση για τη «βιολογική καταπόνηση». Η συνθήκη αυτή, πράγματι, δεν διαφέρει από την καταπόνηση (σωματική ή πνευματική) που υφίσταται οποιοσδήποτε εργαζόμενος και αποτελεί τον λόγο της αμοιβής του.

Ως προς την επιλογή εμβρύου στο πλαίσιο της εξωσωματικής γονιμοποίησης, τέλος, το κοινό φαίνεται να υιοθετεί τις γενικότερα αποδεκτές αξιολογήσεις της ηθικής και του δικαίου, απορρίπτοντας με μεγάλη πλειοψηφία (72%) είτε την επιλογή φύλου, είτε την επιλογή συγκεκριμένων εξωτερικών χαρακτηριστικών (εφόσον αυτή γίνει εφικτή στο μέλλον). Οι απαντήσεις δείχνουν αυξημένη ευαισθησία απέναντι στον κίνδυνο διακρίσεων με βάση τη βιολογία μας ή, με άλλα λόγια, μια ευρύτατη αποδοχή της διαφορετικότητας τουλάχιστον στο πεδίο αυτό. Οι αντιλήψεις της λεγόμενης «φιλελεύθερης ευγονικής» (liberal eugenics), δημοφιλείς σε ορισμένους ακαδημαϊκούς και ερευνητικούς κύκλους (ιδίως στον αγγλοσαξονικό κόσμο), που προωθούν έναν μελλοντικό «σχεδιασμό» των απογόνων μας (designer babies), έχουν ελάχιστους οπαδούς στη δική μας κοινωνία, αν κρίνουμε από την έρευνα αυτή τουλάχιστον.

Τα ευρήματα δείχνουν μια σταθερή κατεύθυνση υπέρ της προσωπικής αυτονομίας με εγγυήσεις διαδικαστικής δικαιοσύνης: πλειοψηφικά δεσμευτικές προγενέστερες οδηγίες (61%) και υψηλή αποδοχή της διακοπής τεχνητής υποστήριξης (60%) υποστηρίζουν το δικαίωμα του ασθενούς να ορίζει το τέλος της ζωής του, ενώ η (μη αμελητέα) αποδοχή της ενεργητικής ευθανασίας (43% + 28% με σύμφωνη γνώμη συγγενών) θέτει ρεαλιστικά ερωτήματα αναλογικότητας, συναίνεσης και επαγγελματικής λογοδοσίας. Η τελευταία νοείται ως υποχρέωση τεκμηριωμένης αιτιολόγησης και ιχνηλασιμότητας των κλινικών πράξεων, με τήρηση πρωτοκόλλων, δυνατότητα δεύτερης γνώμης/παραπομπής όπου αρμόζει και ex post ελεγκτική ανασκόπηση από αρμόδια όργανα. Η επίκληση συνειδησιακής αντίρρησης από τον ασθενή δεν αίρει το καθήκον φροντίδας, αλλά συνεπάγεται έγκαιρη και αποτελεσματική παραπομπή, κάλυψη επειγόντων και διασφάλιση της συνέχειας της περίθαλψης.

Στα θέματα της αναπαραγωγής, η ισχυρή απόρριψη επιλογών που ανοίγουν δρόμο σε δυνητικές διακρίσεις (72% κατά της επιλογής φύλου/χαρακτηριστικών) εναρμονίζει το κοινωνικό αίσθημα με την αρχή της μη-διάκρισης, ενώ οι στάσεις για την παρένθετη μητρότητα (το δικαίωμα της κυοφόρου να κρατήσει το παιδί για περίπου 1/3 των ερωτηθέντων και η έμφαση στην αμοιβή ως εργασία) μετατοπίζουν τη συζήτηση από τον "αλτρουισμό" στα εργασιακά δικαιώματα, την ευαλωτότητα και τη δίκαιη αποζημίωση.

Συνολικά, το κοινό φαίνεται να μη δείχνει προτίμηση σε απαγορεύσεις, ούτε σε "λευκές επιταγές", αλλά σε κανόνες με ρήτρες υπαναχώρησης ή επανεξέτασης, ισχυρή τεκμηριωμένη ατομική συναίνεση, διεπιστημονικές επιτροπές για δύσκολες περιπτώσεις και σαφείς κατευθυντήριες γραμμές

ευθύνης, ώστε η βούληση του προσώπου να προστατεύεται χωρίς να παραβλέπονται οι ευαλωτότητες και οι κίνδυνοι αθέμιτης πίεσης.

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Πρωτότυπες Εργασίες - Original Articles

Πρωτότυπη Εργασία

The cybercriminal risks and threats of body-hacking crimes under the legal framework of Budapest Convention

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Abstract

In this Article, the Budapest Convention (The Convention on Cybercrime, Council of Europe, ETS No. 185) is put under legal analysis in the scope of risks and threats of cybercrimes against implantable, prosthetic and medical devices, referred to as "Body-Hacking Crimes" according to the terminology of this research. To analyze the Budapest Convention systematically, the risks and threats of "Body-Hacking Crimes" are brought to light under three sub-headings (Body-Hacking, Elements of Cybercrimes, Crimes & Reservations) as the main subjects of this Article. Under the first sub-heading, the term "Body-Hacking" is defined and explained as regards of its usage in the general and criminological literature to describe a new category of cybercrimes, as classified "Body-Hacking Crimes" in this paper. Under the second sub-heading, the elements of cybercrimes are analyzed in regard to the substantive law and human rights provisions of the Budapest Convention and legal loopholes regarding body-hacking crimes are uncovered in these provisions. Though there are multiple elements of cybercrimes required to be analyzed in specific to body-hacking crimes, only three elements (Intention, Non-Authorization, Computer Systems) are evaluated under the second sub-heading due to the inadequate regulations and definitions of these elements in the Budapest Convention. Under the final and third sub-heading, computer-related crimes and reservations regulated in the Budapest Convention are examined in correlation with the hackable nature of implantable, prosthetic and medical devices. Particularly, bodily integrity crimes are brought into the focus for legal analysis of body-hacking crimes inducing bodily damage in the final part of this article. In this study, the substantive-law-oriented and definitional problems of the Budapest Convention are predominantly investigated, which results in pointing out mostly Articles 1-13 of Budapest Convention. Furthermore, the domestic laws and court verdicts, esp. UK, US, France and Dutch cybercrime laws and supreme court decisions, are referred in this study to provide a legal perspective regarding the development of body-hacking crimes in the national legislations.

Keywords: the Budapest Convention; cybercrimes; medical devices; body-hacking; the principle of dual criminality.

Οι κίνδυνοι και οι απειλές του κυβερνοεγκλήματος από εγκλήματα body hacking στο πλαίσιο της Σύμβασης της Βουδαπέστης

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Abstract

Στο άρθρο αυτό εξετάζονται από νομική άποψη εγκλήματα στον κυβερνοχώρο κατά εμφυτεύσιμων, προσθετικών και ιατρικών συσκευών, που αναφέρονται ως «εγκλήματα παραβίασης σώματος», σύμφωνα με τη Σύμβαση της Βουδαπέστης (Σύμβαση για το έγκλημα στον κυβερνοχώρο / Συμβούλιο της Ευρώπης). Αναλύονται τα στοιχεία των εγκλημάτων στον κυβερνοχώρο υπό το πρίσμα των διατάξεων του ουσιαστικού δικαίου της Σύμβασης και αποκαλύπτονται τα νομικά κενά που αφορούν τα συγκεκριμένα εγκλήματα στις εν λόγω διατάξεις. Επίσης, εξετάζονται τα εγκλήματα που σχετίζονται με τους υπολογιστές σε συνάρτηση με τις ρυθμίσεις της Σύμβασης για την ευάλωτη φύση των εμφυτεύσιμων, προσθετικών και ιατρικών συσκευών. Ειδικότερα, τα εγκλήματα κατά της σωματικής ακεραιότητας τίθενται στο επίκεντρο της νομικής ανάλυσης. Εξ άλλου, επισημαίνονται εθνικοί νόμοι και δικαστικές αποφάσεις, ιδίως οι νόμοι και οι αποφάσεις των ανώτατων δικαστηρίων του Ηνωμένου Βασιλείου, των ΗΠΑ, της Γαλλίας και των Κάτω Χωρών για τα εγκλήματα στον κυβερνοχώρο, ώστε να μελετηθεί στο συγκεκριμένο πλαίσιο η εξέλιξη των εγκλημάτων σωματικής βίας στα εθνικά νομικά συστήματα.

Λέξεις κλειδιά: Σύμβαση της Βουδαπέστης, εγκλήματα στον κυβερνοχώρο, παραβίαση σώματος, αρχή του διπλού αξιόποινου.

1. Introduction

The integration between body and technology has been improving in correlation with technological developments in biotechnology. The current prostheses, implants, and stimulation devices are more developed and effectively practicable for treating deficient parts of the human body and even enhancing them beyond the edge of human capacity. Moreover, It is no longer a dream to adopt mind-controlled prosthetics, brain-computer interfaces and smart contact lenses, which have succeeded through many examinations and are waiting for industrial production and sale in the near future. Nonetheless, while new technological devices are developed to answer today's problems, they create new risks and threats in parallel with their usage in modern societies. Currently, the most serious threat for medical devices is their hackable nature, and unfortunately, the cybersecurity of these devices is not sufficiently developed to prevent cyberattacks and protect their users 'privacy. Besides technological insufficiencies, legal and administrative remedies are also not well-designed and prepared to deter cybercriminals from illegal access to these devices. Even in the Council of Europe's Convention on Cybercrime (Budapest Convention), which is the most prestigious and accepted Cybercrime Treaty with its 72 party states, there are non-regulated or inadequately regulated parts rendering medical devices and human bodies vulnerable to cyberattacks and leaving cybercriminals released from their actions. In this article, these parts will be spotted and examined in order to assist legislators in eliminating these loopholes and adjusting the Convention more comprehensively. Nonetheless, before the legal examination of the Budapest Convention, the scope of the crimes that are used as the criteria shall be clarified to detect the loopholes in the Budapest Convention. Besides medical devices, prosthetic and implantable devices can also be targeted by cyberattacks which result in serious negative impacts on body functions. Moreover, implantable and prosthetic devices can be used for practical and aesthetic purposes instead of health-related functions, while cyberattacks against them hold the same negative influence on the human body. Since this study aims to deter these consequences by improving the remedial mechanism of the Budapest Convention, the scope of the crimes used as the criteria shall be determined to the extent that covers cybercrimes against all implantable, prosthetic and medical devices, which can create similar consequences to body functions. In the literature, the phrase "hacking human body" is used in the meaning to encompass all cybercrimes against these devices.[1] Hence, the term "body-hacking" is initially analyzed to identify the category of cybercrimes targeting all medical, implantable and prosthetic devices that may have a profound

[1]E. g. Daniel C. Can We Hack the Human Body? LinkedIn, 2022. https://www.linkedin.com/pulse/can-we-hack-human-body-prof-dr-daniel-cebo?utm_source=share&utm_medium=member_ios&utm_campaign=share_via.
Earnhardt R. Hacking the Human Body: The Cyber-Bio Convergance. In Harrigan G. (ed) On the Horizon: Security Challenges at the Nexus of State and Non-State Actors and Emerging/Disruptive Technologies. SMA Periodic Publication, 2019, 32-38. https://nsiteam.com/social/wp-content/uploads/2019/04/DoD_DHS-On-the-Horizon-White-Paper-_FINAL.pdf.
Rauwel G. Body Hackers: Cyber Murders in a Gamer Culture, Kindle: 2015.
Wiles K. Your body is your internet – and now it can't be hacked. Purdue University, 2019. https://www.purdue.edu/newsroom/archive/releases/2019/Q1/your-body-has-internet--and-now-it-cant-be-hacked.html.
Williams S. Three unsafe technologies that could 'hack our bodies'. SecurityBrief UK, 2023. https://securitybrief.co.uk/story/three-unsafe-technologies-that-could-hack-our-bodies.

influence on body functions, as named "Body-Hacking Crimes" in this paper.

2. The Term "Body-Hacking"

2.1. The Primary Meaning of Body-Hacking

Body-hacking refers to the do-it-yourself practice of body modification, made to improve human capacities or change body functions, which intends to expand the boundaries of the human body by surgical implanting of electronic and computing devices into the body.[2] Since the 1990s, it has been promoted and developed due to technological developments and the support of transhumanist and biopunk movements. Especially in parallel to rapid developments in Radio Frequency Identification (RFID) Technology, which uses radio waves to identify people or objects automatically, the body-hacking movement gains more momentum in daily life usage through the adoption of passive RFID implants requiring no battery or any other electric sources implanted in the body.[3] Nonetheless, body-hacking is still an unpopular practice since health facilities do not perform surgeries for body-hacking movement purposes, and self-surgery implantation of devices has low demand for high health risks. As a result, even though there are some technology enthusiasts making self-surgery implantation of devices to modify their bodies for ecstatic or daily usage purposes, the implantation of devices is generally performed for medical purposes to treat bodily disorders or overcome disabilities. On the other hand, RFID implants are vulnerable to cyberattacks like the other types of implantable devices.[4] Hence, although the practice of body-hacking is not addressed in the following parts of the Article, RFID implants adopted for body-hacking purposes are taken up in general and in particular for some cybercrimes against them which are omitted from the jurisdiction of the Budapest Convention.

2.2 Body-Hacking in Criminological Terminology

In general, "hacking" connotes an immoral meaning, being defined as unauthorized and illegal access to systems, networks, or data.[5] Yet,

[2]Giger JC, Gaspar R. A look into future risks: A psychosocial theoretical framework for investigating the intention to practice body hacking. Human Behaviour and Emerging Technologies 2019, 1: 306-307. https://onlinelibrary.wiley.com/doi/epdf/10.1002/hbe2.176.
Jael M. BODY HACKING AND CONCEPTIONS OF CORPOREALITY. Aletheia: The Arts and Science Academic Journal 2022, 2: 52. https://journals.mcmaster.ca/aletheia/issue/view/172/99.

[3]Aubert H. RFID technology for human implant devices. Comptes Rendum Physique 2011, 12: 675-683. https://www.sciencedirect.com/science/article/pii/S1631070511001563.
Mark N Gasson MN, Koops BJ. Attacking Human Implants: A New Generation of Cybercrime. Law, Innovation and Technology 2013, 5: 251-252. http://dx.doi.org/10.5235/17579961.5.2.248.

[4]Kolitz D. Could Someone Hack My Microchip Implant? Gizmodo, 2020, https://gizmodo.com/could-someone-hack-my-microchip-implant-1845216410.

[5]Cambridge Dictionary Online. Hacking. accessed on April 29, 2024.

it can also have an ethical implication in accordance with the context referring to the detection of unintended and deficient parts of a system, network or data and applying them in new and inventive ways to fix these vulnerabilities.[6] In the formation of "body-hacking", hacking primarily adds the latter meaning into this compound word, redefining it in a way that the insufficient and unwanted parts of the body system are adjusted and reconstructed with the process of self-surgery implantation of devices. Nonetheless, it is used in the sense of illegal and unauthorized access to implanted devices and human bodies in the criminological context and literature. In a more ordinary sense, "body-hacking" is also attributed in the criminological literature as the category of cybercrimes targeting implantable, prosthetic and medical devices in parallel to the colloquial meaning of hacking as cyber-offences targeting computer systems.[7] Since the colloquial usage of "body-hacking" reflects the main subject of this study, this term is appealed with a new combined expression as "Body-Hacking Crimes" to stand out its categorical feature and criminal nature.

3. Elements of Cybercrimes

3.1 Intention

Intention is one of the fundamental elements of crimes for the punishment and the conviction of someone in criminal law. As a standard rule, suspects cannot be charged for their actions if they do not intend to engage in criminal behaviors or create unintended effects from their actions. Nevertheless, as an exception to this rule, negligent actions can be criminalized due to the high risk of danger, even if suspects do not intend to act criminally or lead to harmful consequences for someone. In the Budapest Convention, all the crimes mentioned require the intention of criminals in order to be charged against their actions. Nonetheless, body-hacking crimes can result in serious bodily harm up to fatal injuries due to the strong influence of the devices subjected to them on body functions. Especially some medical devices, such as cardiac defibrillators, pacemakers and insulin pumps, can have a decisive role in the stabilization and sustaining of body organ systems, like the blood circulatory system and insulin-glucose system, that a few minutes of their inactiveness can give rise to fatal outcomes. Additionally, undertaking cybercriminal activities against these devices is extremely simple due to their low cybersecurity mechanisms. Until now, only a few cyberattack on medical devices resulting in bodily injury has been detected, yet many studies repeatedly forewarn the users of these devices about how palpable the threat of body-hacking crimes is and

https://dictionary.cambridge.org/dictionary/english/hacking. United Nations Office on Drugs and Crime. Offences against the confidentiality, integrity and availability of computer data and systems. 2019. Accessed on May 1, 2024. https://www.unodc.org/e4j/zh/cybercrime/module-2/key-issues/offences-against-the-confidentiality--integrity-and-availability-of-computer-data-and-systems.html.

[6]Erickson J. Hacking: The Art of Exploitation 2nd ed. No Starch Press, 2008: 1. https://repo.zenk-security.com/Magazine E-book/Hacking- The Art of Exploitation (2nd ed. 2008) - Erickson.pdf.

Jael M, *op.cit.*, p. 54.

IBM. What is ethical hacking? Accessed on April 28, 2024. https://www.ibm.com/topics/ethical-hacking.

[7]Claugh J. Principles of Cybercrime 2nd ed. Cambridge University Press, 2015: 31.

how comparatively easy it is to accomplish. At a Blackberry Security Summit in 2015, Blackberry Chief Security Officer David Kleidermacher and security researcher Graham Murphy demonstrated how hackers could shut down infusion pumps and increase or decrease the medication dosage being delivered with just a network cable and a laptop or tablet.[8] According to the research of McAfee security specialist Barnaby Jack, a cyber-attacker does not even need a network cable to disable the alert feature of insulin pumps and dispense a potentially lethal dose of insulin by only using computer software and a custom-built antenna with a range of 300 feet.[9] In a two-year comprehensive study, Scott Erven, the head of information security for Essentia Health, revealed that cyberattackers could also manipulate Bluetooth-enabled defibrillators to deliver random electric shocks to a patient's heart or prevent a medically needed shock from occurring. As regards the implantable cardiovascular defibrillators, Scott Erven especially noted in his article that defibrillators have default and weak passwords to the Bluetooth stacks, like an iPhone pin that can be guessed with ease.[10]

In light of these studies, it is proven that users of implantable, prosthetic and medical devices are at a high health risk, and several measures are required to be taken. The manufacturers of these devices are trying to improve their cybersecurity systems to prevent cyberattacks against them. Nonetheless, enhanced cybersecurity measures can hamper access to these devices in an emergency. Moreover, enhanced cybersecurity systems produce more energy, so they can slow down medical devices and reduce their usable battery life, leading to more surgical operations to replace these devices and their batteries.[11] Hence, manufacturers generally take a cautious approach towards improving the cybersecurity measures of these devices, which results in infrequent upgrading of the cybersecurity mechanisms. As a substitute for the role of the manufacturers, state authorities undertake the burden of measure implantation by executing their legislative and administrative powers. As an example of these measures, some countries criminalize negligent cyberattacks against these devices resulting in bodily harm to increase the caution of hackers intending harmless actions towards the human body, like illegal access to personal data or interference with data not affecting the function of the devices. For instance, in the Section 161septies of the Dutch Criminal Code and the 3ZA Section of the UK Computer Misuse Act 1990, negligent cyber acts causing or creating a risk of death are

[8]Mottle J. Blackberry Offers Insight On Hidden Security Headaches for Patients. Providers, Fierce Heathcare, 2015. https://www.fiercehealthcare.com/mobile/blackberry-offers-insight-hidden-security-headaches-for-patients-providers.

[9]Kostadinov D. Hacking Implantable Medical Devices. INFOSEC INST, 2014: supra note 47. http://resources.infosecinstitute.com/hcking-implantable-medical-devices/ .

[10]Zetter K. It's Insanely Easy to Hack Hospital Equipment. WIRED, 2014. http://www.wired.com/2014/04/hospital-equipment-vulnerable.

[11]Williams PAH, Woodward AJ. Cybersecurity vulnerabilities in medical devices: a complex environment and multifaceted problem. Dove Press Medical Devices: Evidence and Research 2015: 311. http://dx.doi.org/10.2147/MDER.S50048.

criminalized with the punishment of imprisonment, monetary sanction, or both. In the 3ZA Section of the UK Computer Misuse Act 1990, negligent cyber attacks causing or creating a significant risk of illness and injury are also penalized with the same punishments. Nonetheless, cybercriminal acts can be carried out outside the jurisdiction of the countries while affecting their residents, which enables foreign cybercriminals to commit crimes without paying off for their actions. Hence, state authorities attempt to provide dual criminality with international conventions to avoid the transnational consequences of cybercrimes. As the most ratified cybercrime convention, the Budapest Convention has a vital role in providing dual criminality between sovereign states. Nonetheless, it doesn't include any provision penalizing negligent acts of cybercrime resulting in bodily harm. Furthermore, it is permitted to restrict the scope of the intention in some cybercrimes by filing reservations to several specific articles in the Budapest Convention. For instance, in Articles 2 and 3, a party country may reserve that the offence shall be committed with dishonest intent or with the intent of obtaining data for illegal access. In regard to negligence and intention, the Convention provides discretionary power to its members to regulate their domestic sanctions in accordance with their legal systems. Nevertheless, this discretionary power creates a significant risk for the users of the devices subjected to body-hacking crimes, contradicting one of the primary purposes of the Convention mentioned in the Preamble as *"to pursue, as a matter of priority, a common criminal policy aimed at the protection of society against cybercrime, inter alia, by adopting appropriate legislation and fostering international co-operation"*. Hence, even though this discretionary power can be accepted as a well-placed measure in general, it clearly features an inconsistency with the purpose of the Budapest Convention in particular to body-hacking crimes and requires an adjustment in the Convention in parallel to them.

3.2 Non-authorization and Human Rights

According to Section 1 of the Budapest Convention, every cybercrime necessitates the commission of an act without right. In other words, an act committed with right is not accepted as cybercrime in the Budapest Convention. In the Explanatory Note, though the alternative interpretation by a party state is allowed, the act with right generally refers to *"conduct undertaken with authority (whether legislative, executive, administrative, judicial, contractual or consensual) or conduct that is covered by established legal defences, excuses, justifications or relevant principles under domestic laws"*.[12] In domestic laws, both conducts are prescribed and restricted by legislators to avoid legal uncertainty, disproportionality and exploitation of rights. Nonetheless, while legal defences, excuses, justifications or relevant principles are only executed under extraordinary and exceptional circumstances, authority is a general concept exercised frequently in all positions of society. Furthermore, legal defences, justifications, excuses or relevant principles are only applied to natural persons, exceptionally to commercial legal persons, while authority is generally exerted by government institutions, which also encompass legislative bodies regulating their authorities. Hence, the supervision of authority cannot be effectively ensured by domestic laws, which leads societies as a last safeguard to mainly bind their governments with human rights conventions and empower an independent court to detect breaches of these conventions and

[12]Council of Europe. Explanatory Report to the Convention on Cybercrime. European Treaty Series 2001, 185: 8. https://rm.coe.int/16800cce5b.

punish them for their violations. In the Budapest Convention, although no international court has been established or determined for supervision, the Preamble, Article 15[13], and the Explanatory Report of the Budapest Convention refer to international human rights conventions and instruments for providing safeguards and conditions in implementing the Articles. Hence, authorized acts of cybercrimes in Section 1 of the Convention may be legalized only if they do not violate human rights or their limitations regulated in international instruments. In the current international instruments, most human rights are protected due to the tendency of governments to disregard them and the irrevocable harm of their violations against human individuals. Nevertheless, several human rights are not included in these instruments due to the fear of human rights inflation[14] and up-to-date emergence of them in parallel to social, legal, technological changes and developments. Especially in conjunction with the rapid developments in neurotechnology, new category of human rights have arisen recently, known as "neurorights" in the doctrine that serve as a legal shield against crimes affecting neurofunctional stability of individuals. Nonetheless, most of the neurorights have not been involved in international human rights instruments yet. Despite being recognized as the most well-known neurorights, cognitive liberty, the right to psychological continuity and the right to mental privacy are still not mentioned in any human rights instruments.[15] Mental privacy, as also one of the fundamental neurorights, is only mentioned in the Charter of Fundamental Rights of the European Union and the UN Convention on Rights of Persons with Disabilities, which are

[13]According to Article 15, procedural provisions of the Budapest Convention are subjected to conditions and safeguards mentioned in international human rights instruments. Nonetheless, investigative powers of state authorities to preserve, search, seizure, collect and intercept data are regulated in the Convention's procedural law section. Since authorized access or interception of data are also encompassed in investigative power of state authorities, Article 15 is also cited in this sentence.

[14]*"The objectionable tendency to label everything that is morally desirable as 'human right'. The unjustified proliferation of new rights is indeed problematic because it spreads skepticism about all human rights, as if they were merely wishful thinking or purely rhetorical claims. Right inflation is to be avoided because it dilutes the core idea of human rights and distracts from the central goal of human rights instruments, which is to protect a set of truly fundamental human interests, and not everything that would be desirable or advantageous in an ideal world."*
Ienca M, Andorno R. Towards new human rights in the age of neuroscience and neurotechnology. Life Sciences, Society and Policy 2017, 13: 9. https://doi.org/10.1186/s40504-017-0050-1.

[15]Bublitz JC, Merkel R. Crimes Against Minds: On Mental Manipulations, Harms and a Human Right to Mental Self-Determination. Criminal Law and Philosophy 2014, 8: 60 51–77. https://doi.org/10.1007/s11572-012-9172-y. Istace T. Protecting the mental realm: What does human rights law bring to the table? Netherlands Quarterly of Human Rights 2023, 41: 216. https://doi.org/10.1177/09240519231211823.
Ligthart S. Towards a Human Right to Psychological Continuity? Reflections on the Rights to Personal Identity, Self-Determination, and Personal Integrity. European Convention on Human Rights Law Review 2024, 5: 205. https://doi.org/10.1163/26663236-bja10092.

found insufficient and criticised for not referring to neurotechnology-related practices or particular harms resulted by malevolently interfering with a person's neuropsychological sphere.[16] Under the current circumstances, even though the well-known fundamental human rights and freedoms, such as the freedom of thought, the right to privacy, etc., lay the foundation for neurorights, they cannot provide sufficient protection for individuals against brain data violations, cyber-attacks to neurosystems, manipulative and authoritative interventions to personal identity, psychology and autonomy. Since the existence of neurorights is built upon the purpose of preventing the similar violations and interventions mentioned in the previous sentence, the inclusion of neurorights in the human rights instruments is required for the ideal protection of individuals against ill-intentioned governments and persons.[17] Nonetheless, as no current human rights instruments contain the neurorights, except mental integrity, in their context, the safeguards and conditions mentioned in the Budapest Convention do not apply to authorized acts of body-hacking crimes which attack or interfere with brain implants and impact the personal autonomy, identity, psychology, brain data and similar aspects of the human mind.

3.3 Computer Systems

In the Budapest Convention, "computer systems" are defined as *"any device or a group of interconnected or related devices, one or more of which, pursuant to a program, performs automatic processing of data"*. Despite its name, computer systems do not only include computers in their extent. Mobile phones, tablets, Internet of Things (IoT) and medical devices are also within the scope of the term.[18] As a matter of fact, only two functional qualities are required to be recognized as a computer system according to the Convention: being pursuant to a program and performing automatic data processing. Similar to many technological devices, most of the devices subjected to body-hacking crimes hold these qualities and are competent to be acknowledged as computer systems. Nonetheless, some versions of these devices, especially the old ones, are not capable of processing data. For instance, some models of passive RFID implants, cognitive prostheses, DBS devices, pacemakers and cardiac defibrillators can only be qualified as simple data storage devices, not as computer systems.[19] Nevertheless, these devices can still benefit from the legal protection of the Convention since the definition of a computer system includes a group of devices of which at least one device processes data; computers consist of a processing unit and peripherals. Hence, a storage device can be a part of a computer system as a peripheral, which is part of a group of devices.[20] There is a Dutch Supreme Court verdict supporting that a device does not have to possess the mandatory functionalities

[16]Ienco M. Common Human Rights Challenges Raised By Different Applications of Neurotechnologies in the Biomedical Fields. Committee on Bioethics of Council of Europe, 2021: 51-52. https://rm.coe.int/report-final-en/1680a429f3#page51.
[17]Ienca M, Andorno R. *op. cit.*, pp. 23-24.
[18]Claugh J, *op. cit.*, pp. 59-68.
[19]Gasson MN, Koops BJ, *op. cit.*, p. 267.
[20]Council of Europe, *op. cit.*, p. 5.

(storing, processing, and transferring in Dutch Law) of a computer in itself, but rather, the combination of devices constituting a computer system should have these functionalities.[21] In that case, the Convention still provide protection if the implant is considered part of a group of devices. Passive RFID implants can only function in conjunction with a reading device, which has the capacity to process data, resulting in being qualified as part of a computer system. Deep brain stimulation devices, cognitive prostheses, pacemakers, and cardiac defibrillators can also benefit from the protection of the Convention by having the capacity to process data or being part of a group of devices that involves a data-processing device. Nonetheless, the older models of pacemakers and cardiac defibrillators consist only of pulse generators, electrodes, and some small storage capacity devices, making them insufficient to achieve the threshold of a data processing device.[22] Also, interpreting the mentioned devices as part of a computer system is open to the preference of party states. Consequently, no legal assurance exists that all devices exposed to body-hacking crimes will fall within the protective scope of the legal framework established by the Budapest Convention.

4. Crimes & Reservations

4.1 Cybercrimes in the Budapest Convention

In the Budapest Convention, only the common types of cybercrimes are defined and regulated in Article 2 through Article 11. As an international instrument, it is an obligatory characteristic of the Budapest Convention to be flexible and broadly applicable so that state authorities can recognize and enforce them without reluctance. Hence, as the category of cybercrimes that no incident regarding them has been detected yet, it is acceptable that the Council of Europe did not regulate body-hacking crimes and take them into account in the draft process of the Budapest Convention.[23] Nonetheless, body-hacking crimes pose a significant risk to human health and can produce severe bodily damage that may lead to the loss of human life. Even though a few incidents of body-hacking crimes has occurred before, the more prevalent usage of wireless and BCI (Brain-Computer Interface) technology in implantable, prosthetic and medical devices will enhance their hackability potential in the near future. The risks of body-hacking crimes cannot be disregarded due to these reasons; thus, the Budapest Convention still requires several amendments in order to provide full-fledged protection for these device users. As the first proposed amendment, the current cybercrimes pointed out in the Budapest Convention shall be re-regulated to the degree that unquestionably eliminates the risks of body-hacking crimes. In the Convention, several substantive-law provisions involve the risks of body-hacking crimes due to their incompetent regulation. For instance, Article 5, which regulates the cybercrime of system interference, only criminalizes interferences that seriously hinder

[21]Gasson MN, Koops BJ, *op. cit.*, p. 267.
Hoge Raad [Dutch Supreme Court], March 26, 2013, LJN BY9718.
[22]*Idem*, p. 268.

[23]Browning JG, Tuma S, *op. cit.*, p. 638. https://scholarcommons.sc.edu/cgi/viewcontent.cgi?article=4183&context=sclr.

the functioning of computer systems. In other words, it permits member states to exempt cyber acts that hinder the functioning of computer systems lightly but induce serious harm or threat to the human body from punishment. As another example, Article 10, which regulates the offences related to infringements of copyright and related rights, penalizes the violations of the rights associated with intellectual property which is expressed in accordance with several international conventions[24] mentioned in this article. Nonetheless, it is questionable whether human thoughts and memories stored in the brain implants must be accepted as expressed per the mentioned conventions. These conventions do not include any clause regarding the automatic expression of human thought or memory stored in brain implants. Hence, it is possible that state authorities interpret these conventions alternatively and decide to exclude the infringement of human thought and memory from the scope of Article 10. Nevertheless, the infringement of human memory and thought can award the perpetrators enormous gains on the economic scale. For instance, a memory of a famous person in his brain implant can be merchandized and distributed like a movie or a documentary, or the thought of an individual stored in his brain implant can lead to a miraculous invention and gain enormous money to its possessor. Even though illegal access to brain implants is penalized under Article 2 of the Budapest Convention, the unlawful economic usage of human memory and thought cannot be criminalized by the following articles of Budapest Convention besides Article 10. Illegal economic use of intellectual property forms another act of crime and might receive more severe punishments due to their important role in the economic and intellectual development of societies. In order to provide just and fair punishment for this cybercriminal act, Article 10 shall be modified to the extent that human thought and memory are protected against intellectual property rights infringements. Hence, an additional intellectual property convention that covers human memory and thought in brain data under the scale of intellectual property rights can be included in the agreements listed in Article 10, or particular regulation in regards to it might be added in this article.

As per the second proposed amendment, body-hacking crimes shall be regulated specifically in the substantive law section of the Budapest Convention. A general provision regarding cybercrimes inducing bodily damage can be inserted for the overall health risks of body-hacking crimes discussed above. Nevertheless, several specific body-hacking crimes possess unique characteristics engendering consequences that extend beyond psychological and physical damage. As an example of these crimes, brainjacking, the exercise of unauthorized control of another's electronic brain implant, shall be explicitly regulated due to its particular consequences on the human body, emotions and autonomy.[25]

[24]Paris Act of 24 July 1971 Revising the Berne Convention for the Protection of Literary and Artistic Works, International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations (Rome Convention), the Agreement on Trade-Related Aspects of Intellectual Property Rights, WIPO Copyright Treaty and WIPO Performances & Phonograms Treaty.

[25]Pugh J et al. Brainjacking in deep brain stimulation and autonomy. *Ethics and Information Technology*

Similar to other body-hacking crimes, brainjacking can cause physical damage to brain tissue and prevent a programmed medical treatment of brain implants by overcharging them.[26] Nonetheless, it can also lead to the dysfunction of emotional behaviour for the brain implant users and induce unbearable pain in them without requiring a physical injury, such as by increasing the frequency of PAG/PVG stimulation.[27] In the worst scenario, brain implants pave the way for brainjackers to control the users' minds or bodies by sending calibrated electrical impulses to the brain and motor nerves. Brainjackers can influence decisional autonomy in addition to practical autonomy.[28] Though they cannot mainly take part in the decision-making process, they may foster an intention to commit a crime by targeting their users' reward systems and emotions.[29] Nonetheless, brainwashing (mind control) is not recognized as a crime and a legal defence in most national legislations and the Budapest Convention. Except for a few national laws, such as the About-Picard Law in France, most countries do not penalize the sole act of brainwashing and do not uphold it as a legal defence to the criminal liability of the victims.[30] By an explanation of it, it is argued that the theory of brainwashing is not dominantly accepted in the scientific field of psychology due to the lack of empirical data.[31] The traditional methods used in brainwashing and their effects on the victims cannot be empirically analyzed due to the illegality of experimenting with these methods and the complexity of observing the deterministic relationship between them. However, as a procedural obligation, brain implant patients are strictly monitored by advanced medical devices periodically after their surgeries, which provokes the accumulation of great quantities of empirical data. Moreover, the effects of brain implants on the brain are direct, immediate and first-hand. They can also be easily observed due to the trackability of implanted devices and electrodes that monitor

2018, 20: 219. https://doi.org/10.1007/s10676-018-9466-4.

[26]Pycroft L et al. Brainjacking: Implant Security Issues in Invasive Neuromodulation. World Neurosurgery 2016, 92: 455-456. http://dx.doi.org/10.1016/j.wneu.2016.05.010.

[27]*Ibid*, p. 456-457.

Pugh J et al., *op. cit.*, pp. 221-226.

[28]*Ibid*, p. 226.

[29]*Ibidem*.

Pycroft L et al., *op. cit.*, p. 457.

[30]For instance, the criminal legal systems of the United States and Canada, which are the signatory countries of the Budapest Convention, do not acknowledge brainwashing as a legitimate defence for exemption from criminal liability.

Chapman FE. Intangible Captivity: The Potential for a New Canadian Criminal Defense of Brainwashing and Its Implications for the Battered Woman. Berkeley Journal of Gender, Law & Justice 2013, 28: 74. https://doi.org/10.15779/Z38RR1PM1J.

Emory R. Losing Your Head in the Washer – Why the Brainwashing Defense Can Be a Complete Defense in Criminal Cases. Pace Law Review 2010, 30: 1355. https://doi.org/10.58948/2331-3528.1742.

[31]American Psychological Association hasn't accepted brainwashing as a scientific theory.

Warburton ID. The Commandeering of Free Will: Brainwashing as a Legitimate Defense. Capital Defense Journal 2003, 16: 78-79. https://scholarlycommons.law.wlu.edu/wlucdj/vol16/iss1/6.

Emory R, *op. cit.*, p. 1355.

and transmit brain electrical impulses.[32] Hence, the arguments about the unscientific nature of brainwashing methods cannot be given credit in the case of mind control with brain implants. Without any objections, the effects of brain implants on autonomy are scientifically accepted and discussed academically.[33] In a position where science acknowledges the threat of brain implants on autonomy, it would be irrational for legal systems to ignore it and not take any precautions against it. Particularly in conjunction with the rapid advancements in Brain-Computer Interface (BCI) technology, the potential risks associated with brain implants on individual autonomy may increase significantly in the future. Hence, the basic precautionary actions for criminalization and legal excuse for mind manipulation shall at least be taken in domestic laws and the Budapest Convention.

4.2 Bodily Integrity Crimes

As noted in the former section, body-hacking crimes can lead to severe bodily harm due to the impact these devices exert on bodily functions. By deactivation or malfunction of medical devices, a third person can easily interrupt the infusion of a hormone, drug or biochemical fluid that is used to stabilize homeostatic balance or the delivery of electric shocks towards the human heart functioning to correct cardiac arrhythmia, which serves as a reason for that the former US Vice President Dick Cheney disabled his pacemaker's wireless capabilities in 2012.[34] With the aim of mitigating the bodily risks and threats of body-hacking crimes, some state authorities adopt legislative measures to penalize the cybercrimes contributing to bodily harm. For instance, in the 18 U.S. Code §§ 1030(c)(4)(A), the 3ZA Section of the UK Computer Misuse Act 1990 and Section 161sexies of the Dutch Penal Code, cyber acts inducing bodily damage are criminalized with up to imprisonment, monetary penalty, or both. Nonetheless, not all domestic laws encompass specific provisions to penalize these cyber acts. Furthermore, the criteria for bodily damage and acts of cybercrime generally vary in domestic laws. As an example, the 18 U.S. Code §§ 1030 penalizes both illegal access and system interference producing physical injury (at all degree) while the Dutch Penal Code criminalizes only system interferences required to endanger a human life and UK Computer Misuse Act proscribes any unauthorised act in relation to a computer creating a serious injury or illness. As it can be observed from these three different regulations, the application of dual criminality on cybercrimes inducing bodily damage is generally a challenging issue, requiring an international agreement on several points of them to block transnational cybercrimes and secure the users of medical devices to a global extent. Yet, the Budapest Convention and other cybercrime

[32]Jonathan Pugh et al., *op. cit.,* 221.
Quirin T et al. Towards Tracking of Deep Brain Stimulation Electrodes Using an Integrated Magnetometer. Sensors 2021, 21: 1-2. https://doi.org/10.3390/s21082670.

[33]Koivuniemi A, Otto K. When "altering brain function" becomes "mind control". frontiers in SYSTEMS NEUROSCIENCE 2014, 8: 1.
Pugh J et al., *op. cit.*, 219–226.

[34]Browning JG, Tuma S. If Your Heart Skips a Beat, It May Have Been Hacked: Cybersecurity Concerns with Implanted Medical Devices. South Carolina Law Review 2016, 67: 638. https://scholarcommons.sc.edu/cgi/viewcontent.cgi?article=4183&context=sclr.

conventions, as being the most effective instrument for ensuring the principle of dual criminality between national legislations, do not include any specific regulation on the subject of cybercrimes inducing bodily harm. In all probability, international commissions can assume that cybercrimes inducing bodily harm are covered by battery or assault laws, which are prescribed and regulated in almost all national legislations, requiring no additional adjustment for cybercrimes inducing bodily harm. Nevertheless, these bodily integrity crimes carry out different features and characteristics than cybercrimes inducing bodily harm. For instance, battery and assault laws subject the crimes that attack the human body, not implants or any other devices. Hence, it is questionable whether implantable, prosthetic and medical devices can be accepted as a part of the body in the context of laws. There are some court cases in France and the Netherlands that treat dental prostheses and teeth implants as an integral part of the human body.[35] By making an analogy, it can be argued that pacemakers, cardiac defibrillators, cochlear implants and other implantable medical devices shall be accepted as part of the human body. Yet, prosthetic limbs are not accepted as human body parts in some court cases, which hardens to protect bionic arms and network cognitive prostheses under the category of assault and battery laws.[36] Moreover, it is also questionable to what extent the neural system is covered by bodily integrity, which determines the legal status of attacks on the brain and neural implants. In the UK and the Netherlands, bodily injuries amount to recognizable psychiatric conditions are covered by battery laws, while the lesser conditions are not.[37] Hence, non-consensual mental infringements, like sending signals to the brain through electronic interference with an implant, are not covered by battery laws, while physical infringements (such as spitting, touching or kissing) are covered by them.[38] Besides setting the bodily borders for the protection of the law, the type of contact and injury for committing battery and assault crimes can also be determinant in the application of cyberattacks against medical implants. Normally, physical contact is sought in the commission of battery and assault crimes, but it is not a prerequisite for the occurrence of them, according to UK and US Case Law.[39] The real

[35]Akmazoglu TB, Chandler JA. Mapping the emerging legal landscape for neuroprostheses: Human interests and legal resources. Hevia M (ed) In Developments in Neuroethics and Bioethics Volume 4. Academic Press, 2021: 83. https://www.sciencedirect.com/science/article/pii/S2589295921000072?ref=cra_js_challenge&fr=RR-1.
Gerechtshof [Court of Appeal] Amsterdam 21 February 2013, LJN BZ2055 [NL].
Rechtbank [District Court] Zutphen 9 February 2010, LJN BL3094.

[36]Browns B. A Farewell to Arms (And Legs): The Legal Treatment of Artificial Limbs. Columbia Journal of Law and Social Problems 2013, 47: pp. 88 and 98. https://jlsp.law.columbia.edu/wp-content/blogs.dir/213/files/2017/03/47-Brown.pdf.
State v. Schaffer, 202 Ariz. 592, 48 P.3d 1202 (Ariz. Ct. App. 2002).

[37]The Crown Prosecutive Service (CPS). Offences against the Person, incorporating the Charging Standard. last updated June 27, 2022. https://www.cps.gov.uk/legal-guidance/offences-against-person-incorporating-charging-standard.
Gasson MN, Koops BJ, *op. cit.*, 273.

[38]*Ibid*, 273.

[39]*Ibid*, 273.

problem is that the criminalization of wounding is much more physically formulated, as it requires an injury that breaks both the outer and inner skin. Attacks on bodily implants will not result in skin injuries, and thus cannot be interpreted as wounding.[40] Nonetheless, several criminal legislations demand crimes to fall within the description of wounding to impose more severe sentences on the criminals. For instance, the Virginia Criminal Code distinguishes wounding (§ 18.2-51) from assault and battery offences (§ 18.2-57), which include only monetary and confinement sanctions for a maximum of 5 years compared to wounding, whose sentence can last up to 20 years imprisonment. Hence, even though national criminal provisions generally encompass general terms to define assault and battery offences,[41] cybercriminals inducing serious bodily damage might not be exposed to severe punishments due to the definitional block of wounding, though they create similar serious consequences to it. In order to provide fair and reasonable punishment to these cybercriminal acts, several national legislations, like Section 20 in UK Offences against the Person Act 1861, broaden the scope of criminal acts in the criminal provisions regarding wounding offences or regulate these acts in separate clauses with similar penalties. Nonetheless, it is not a standard practice between national legislations, so the global nature of cybercrimes can lead to complex applications of their penal codes, which can be concluded with shorter periods of punishment than what the criminals deserve. As mentioned above, the subjects of assault and battery laws are also regulated uniquely based on the laws of countries which produce the same legal complexity and inefficiency in the application of national criminal laws. As a result, mutual cooperation in legislation is also required for assault and battery laws to prevent global consequences of body-hacking crimes.

4.3 Reservations

The incompetent provisions of the Budapest Convention fall body-hacking crimes in a restricted regulatory framework that only apply when they display general characteristics of computer-related crimes prescribed in the Convention. Nevertheless, this narrow scope of the Convention can be limited more by the reservations of the affiliated states allowed in the specific clauses. For instance, according to Article 2, a party state may reserve that the offence of illegal access shall be committed by only infringing security measures. Nonetheless, many implantable medical devices, particularly the older generations, do not possess any security

DPP v K [1990] Cr App R 23.

Fisher v Carrousel Motor Inc., Supreme Court of Texas, 424 S.W.2d 627 (1967).

Bublitz C. The body of law: boundaries, extensions, and the human right to physical integrity in the biotechnical age. Law and the Biosciences 2022, 9: 7. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9621699/pdf/lsac032.pdf.

[40]Gasson MN,Koops BJ, *op. cit.,* 273.

[41]For instance, Dutch Criminal Law uses the term mishandeling (maltreatment) in assault and battery provisions, which allows courts to interpret the actions of criminals broadly.

Teunissen M. Mishandeling versus Assault: A comparative Approach. Master's Thesis, Leiden University, 2017: 38. https://studenttheses.universiteitleiden.nl/access/item:2607954/view.

mechanism at all.[42] Hence, these devices may end up totally defenseless against hacking incidents with this reservation, which may give rise to high-impact disclosures of sensitive personal data stored and processed in these devices. As another example, the criminalization of an attempt to commit any offences mentioned in this Convention can be avoided by the reservation of a party state based on Article 11. By taking account of the possible consequences of an attempted cyberattack against implantable, prosthetic and medical devices with the intention to murder or assault, giving a right to reservation on attempted offences puts the users of these devices at significant risks and under a great fear of injury. As aware of these risks and fear, most countries penalize attempted crimes inducing severe bodily damage in their criminal laws, which seems devaluing the right to reservation regarding attempted body-hacking crimes. Nonetheless, the legal criteria for the acceptance of an action as an attempted crime can vary according to domestic laws. Hence, this situation may lead to a serious struggle for mutual assistance between the party states since the Convention gives party states the right to refuse a request for mutual assistance in its several provisions based on the unfulfillment of dual criminality. For instance, Article 29(4) gives party states a reservation right to refuse data preservation requests based on the unfulfillment of dual criminality for offences other than those established in accordance with Article 2 through Article 11 of the Convention. The condition of dual criminality is deemed to automatically met between the party states for the offences regulated in Article 2 through Article 11, subject to any reservations the affiliated states may have made regarding these offenses where permitted by the Convention.[43] Thereby, the reservation on an attempted crime in Article 11 can invalidate this assumption of dual criminality, retaining the right to refuse data preservation requests. As the preservation request is the key element for other mutual assistance procedures regarding investigative powers, the reservation right on Article 11(3) of the Convention might constitute a significant obstacle for requesting countries in their criminal investigations on attempted cybercrimes. Not only reservation on Article 11(3) but also reservation on Article 4(2) (Data interference only resulting in serious harm), Article 6(3) (Several types of misuse of devices), Article 9(4) (Several offences related to child pornography) and Article 10(3) (Limited circumstances for criminal liability of offenders infringing intellectual property rights) can also constitute this obstacle for requesting countries for their criminal investigations. On account of standard types of cybercrimes, these reservations might be tolerated due to their material kind consequences at most they can result. Nonetheless, body-hacking crimes may lead to health-related consequences that cannot be tolerated in any manner. Hence at least, the Budapest Convention shall keep several reservations out-of-application in regards to body-hacking crimes which endanger human life to the degree that the reservation of them is intolerable in any form.

[42]Núñez CC. Cybersecurity in Implantable Medical Devices. Doctoral Thesis, Universidad Carlos III de Madrid, 2017: 18. chrome://external-file/tesis_carmen_camara_nunez_2018.pdf.

[43]Council of Europe, *op. cit.*, p. 51.

5. Conclusion

In this Research Paper, the cybercriminal risks and threats associated with body-hacking crimes were analyzed under the legal scope of the Budapest Convention. By the conclusion of this legal analysis, it has been figured out that the regulations of the Budapest Convention had been prepared without a comprehensive consideration of cybercrimes against implantable, prosthetic and medical devices in regard to their health-related risks and consequences. By taking the fact that a few incident regarding these cybercrimes has occurred only, it may seem unreasonable to take these crimes into account within the structure of the Budapest Convention. But as explained in this study, these cybercrimes can result in detrimental consequences with respect to human health, personal privacy, bodily integrity and fundamental human rights. Hence, it is crucial to maintain prohibitive and restrictive provisions against these crimes as the precautionary resort within the framework of the Budapest Convention. At this time, it is impossible to alter the textual structure of the Budapest Convention as it has been years since the Budapest Convention was adopted on 23 November 2001. Nonetheless, new protocols regarding the Convention can be issued to modify it, like Council of Europe did in First & Second Protocols to the Budapest Convention. Currently no preparation of Council of Europe is observed for the composition of a new protocol regarding the Budapest Convention. Hence, this study actually serves as a call to action for lawmakers, international organizations, and state officials to proactively integrate these mentioned cybercriminal threats into the legal scope of the Budapest Convention. In that way, it is intended to maintain the Budapest Convention as a relevant and effective tool in the fight against cybercrimes and ensure the proper legal protection of the users of these devices.

Bibliography

Akmazoglu TB, Chandler JA. Mapping the emerging legal landscape for neuroprostheses: Human interests and legal resources. Hevia M (ed) In Developments in Neuroethics and Bioethics Volume 4. Academic Press, 2021: 63-98. https://www.sciencedirect.com/science/article/pii/S2589295921000072?ref=cra_js_challenge&fr=RR-1.

Aubert H. RFID technology for human implant devices. Comptes Rendum Physique 2011, 12: 67-683. https://www.sciencedirect.com/science/article/pii/S1631070511001563.

Browning JG, Tuma S. If Your Heart Skips a Beat, It May Have Been Hacked: Cybersecurity Concerns with Implanted Medical Devices. South Carolina Law Review 2016, 67: 637-677. https://scholarcommons.sc.edu/cgi/viewcontent.cgi?article=4183&context=sclr.

Browns B. A Farewell to Arms (And Legs): The Legal Treatment of Artificial Limbs. Columbia Journal of Law and Social Problems 2013, 47: 69-102. https://jlsp.law.columbia.edu/wp-content/blogs.dir/213/files/2017/03/47-Brown.pdf.

Bublitz C. The body of law: boundaries, extensions, and the human right to physical integrity in the biotechnical age. Law and the Biosciences 2022, 9: 1-26. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9621699/pdf/lsac032.pdf.

Bublitz JC, Merkel R. Crimes Against Minds: On Mental Manipulations, Harms and a Human Right to Mental Self-Determination. Criminal Law and Philosophy 2014, 8: 51-77. https://doi.org/10.1007/s11572-012-9172-y.

Cambridge Dictionary Online. Hacking. https://dictionary.cambridge.org/dictionary/english/hacking.

Chapman FE. Intangible Captivity: The Potential for a New Canadian Criminal Defense of Brainwashing and Its Implications for the Battered Woman. Berkeley Journal of Gender, Law & Justice 2013, 28: 31-76. https://doi.org/10.15779/Z38RR1PM1J.

Claugh J. Principles of Cybercrime 2nd ed. Cambridge University Press, 2015.

Committee for Scientific and Technological Policy. Recommendation of the Council on

Responsible Innovation in Neurotechnology. OECD, 2019. https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0457.

Council of Europe. Explanatory Report to the Convention on Cybercrime. European Treaty Series 2001, 185. https://rm.coe.int/16800cce5b.

Daniel C. Can We Hack the Human Body? LinkedIn, 2022. https://www.linkedin.com/pulse/can-we-hack-human-body-prof-dr-daniel-cebo?utm_source=share&utm_medium=member_ios&utm_campaign=share_via.

DPP v K [1990] Cr App R 23.

Earnhardt R. .Hacking the Human Body: The Cyber-Bio Convergance. In Harrigan G. (ed) On the Horizon: Security Challenges at the Nexus of State and Non-State Actors and Emerging/Disruptive Technologies. SMA Periodic Publication, 2019: . https://nsiteam.com/social/wp-content/uploads/2019/04/DoD_DHS-On-the-Horizon-White-Paper-_FINAL.pdf.

Emory R. Losing Your Head in the Washer – Why the Brainwashing Defense Can Be a Complete Defense in Criminal Cases. Pace Law Review 2010, 30: 1337-1359. https://doi.org/10.58948/2331-3528.1742.

Erickson J. Hacking: The Art of Exploitation 2nd ed. No Starch Press, 2008.

https://repo.zenk-security.com/Magazine E-book/Hacking- The Art of Exploitation (2nd ed. 2008) - Erickson.pdf.

Fisher v Carrousel Motor Inc., Supreme Court of Texas, 424 S.W.2d 627 (1967).

Gasson MN, Koops BJ. Attacking Human Implants: A New Generation of Cybercrime. Law, Innovation and Technology 2013, 5: 248-277. http://dx.doi.org/10.5235/17579961.5.2.248.

Gerechtshof [Court of Appeal] Amsterdam 21 February 2013, LJN BZ2055 [NL].

Giger JC, Gaspar R. A look into future risks: A psychosocial theoretical framework for investigating the intention to practice body hacking. Human Behaviour and Emerging Technologies 2019, 1: 306-310. https://onlinelibrary.wiley.com/doi/epdf/10.1002/hbe2.176

Hoge Raad [Dutch Supreme Court], March 26, 2013, LJN BY9718.

IBM. What is ethical hacking? https://www.ibm.com/topics/ethical-hacking.

Ienca M, Andorno R. Towards new human rights in the age of neuroscience and neurotechnology. Life Sciences, Society and Policy 2017, 13: 1-27. https://doi.org/10.1186/s40504-017-0050-1.

Ienco M. Common Human Rights Challenges Raised By Different Applications of Neurotechnologies in the Biomedical Fields. Committee on Bioethics of Council of Europe, 2021. https://rm.coe.int/report-final-en/1680a429f3#page51.

Istace T. Protecting the mental realm: What does human rights law bring to the table? Netherlands Quarterly of Human Rights 2023, 41: 179-260. https://doi.org/10.1177/09240519231211823.

Jael M. BODY HACKING AND CONCEPTIONS OF CORPOREALITY. Aletheia: The Arts and Science Academic Journal 2022, 2: 52-61. https://journals.mcmaster.ca/aletheia/issue/view/172/99.

Kolitz D. Could Someone Hack My Microchip Implant? Gizmodo, 2020, https://gizmodo.com/could-someone-hack-my-microchip-implant-1845216410.

Koivuniemi A, Otto K. When "altering brain function" becomes "mind control". frontiers in SYSTEMS NEUROSCIENCE 2014, 8: 1-6. doi: 10.3389/fnsys.2014.00202

Kostadinov D. Hacking Implantable Medical Devices. INFOSEC INST, 2014. http://resources.infosecinstitute.com/hcking-implantable-medical-devices/.

Ligthart S. Towards a Human Right to Psychological Continuity? Reflections on the Rights to Personal Identity, Self-Determination, and Personal Integrity. European Convention on Human Rights Law Review 2024, 5: 199-229. https://doi.org/10.1163/26663236-bja10092.

Mottle J. Blackberry Offers Insight On Hidden Security Headaches for Patients. Providers, Fierce Heathcare, 2015.

https://www.fiercehealthcare.com/mobile/blackberry-offers-insight-hidden-security-headaches-for-patients-providers.

Núñez CC. Cybersecurity in Implantable Medical Devices. Doctoral Thesis, Universidad Carlos III de Madrid, 2017. chrome://external-file/tesis_carmen_camara_nunez_2018.pdf.

Pugh J et al. Brainjacking in deep brain stimulation and autonomy. Ethics and Information Technology 2018, 20: 219-232. https://doi.org/10.1007/s10676-018-9466-4.

Pycroft L et al. Brainjacking: Implant Security Issues in Invasive Neuromodulation. World Neurosurgery 2016, 92: 454-462. http://dx.doi.org/10.1016/j.wneu.2016.05.010.

Quirin T et al. Towards Tracking of Deep Brain Stimulation Electrodes Using an Integrated Magnetometer. Sensors 2021, 21: 1-18. https://doi.org/10.3390/s21082670.

Rauwel G. Body Hackers: Cyber Murders in a Gamer Culture, Kindle: 2015.

Rechtbank [District Court] Zutphen 9 February 2010, LJN BL3094.

State v. Schaffer, 202 Ariz. 592, 48 P.3d 1202 (Ariz. Ct. App. 2002).

The Crown Prosecutive Service (CPS). Offences against the Person, incorporating the Charging Standard. https://www.cps.gov.uk/legal-guidance/offences-against-person-incorporating-charging-standard.

Teunissen M. Mishandeling versus Assault: A comparative Approach. Master's Thesis, Leiden University, 2017. https://studenttheses.universiteitleiden.nl/access/item:2607954/view.

United Nations Office on Drugs and Crime. Offences against the confidentiality, integrity and availability of computer data and systems. 2019. https://www.unodc.org/e4j/zh/cybercrime/module-2/key-issues/offences-against-the-confidentiality--integrity-and-availability-of-computer-data-and-systems.html.

Warburton ID. The Commandeering of Free Will: Brainwashing as a Legitimate Defense. Capital Defense Journal 2003, 16: 73-97. https://scholarlycommons.law.wlu.edu/wlucdj/vol16/iss1/6.

Wiles K. Your body is your internet – and now it can't be hacked. Purdue University, 2019. https://www.purdue.edu/newsroom/archive/releases/2019/Q1/your-body-has-internet--and-now-it-cant-be-hacked.html.

Williams PAH, Woodward AJ. Cybersecurity vulnerabilities in medical devices: a complex environment and multifaceted problem. Dove Press Medical Devices: Evidence and Research 2015: 305-316. http://dx.doi.org/10.2147/MDER.S50048.

Williams S. Three unsafe technologies that could 'hack our bodies'. SecurityBrief UK, 2023. https://securitybrief.co.uk/story/three-unsafe-technologies-that-could-hack-our-bodies.

Zetter K. It's Insanely Easy to Hack Hospital Equipment. WIRED, 2014. http://www.wired.com/2014/04/hospital-equipment-vulnerable.

On the risisng costs of veterinary care and the legal and ethical implications for pet animal welfare

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Abstract

The sharp rise in veterinary care costs across Europe in recent years has created significant ethical and legal challenges concerning the welfare of pet animals. Since animals are recognized as sentient beings in both legal and ethical terms, the inability of many pet owners to access necessary veterinary care raises concerns about the broader consequences for animal welfare.

While inflation and technological innovation contribute to rising costs, many countries identify aggressive market consolidation by a few corporate actors as the primary cause. These dominant players reduce competition and limit price transparency, creating conditions that put animal welfare at risk by discouraging timely and affordable access to care, while also undermining veterinarians' ability to operate independently and ethically.

In response, various legislative initiatives have been introduced. Germany enforces a fee schedule to regulate veterinary pricing; Greece has established municipal veterinary services for disadvantaged groups; the United Kingdom is investigating anti-competitive practices in the sector; and the United States of America has proposed tax deductions for veterinary expenses. These examples reflect differing approaches to distributing responsibility between the state, the profession, and pet owners.

To ensure long-term access to veterinary care and uphold animal welfare obligations, the report recommends a multifaceted regulatory strategy. This includes transparent pricing, proportional fee regulation, targeted public services, and safeguards against excessive market concentration. Rather than relying on one actor alone, a shared responsibility model is needed to ensure that economic barriers do not undermine legal and ethical commitments to protect animal welfare.

Keywords: Animal welfare law, veterinary care, market competition, fair pricing, bioethics.

Σχετικά με την αύξηση του κόστους της κτηνιατρικής περίθαλψης και τις νομικές και ηθικές επιπτώσεις για την ευημερία των κατοικίδιων ζώων

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Περίληψη

Η απότομη αύξηση του κόστους των κτηνιατρικών υπηρεσιών σε όλη την Ευρώπη τα τελευταία χρόνια έχει δημιουργήσει σημαντικές ηθικές και νομικές προκλήσεις όσον αφορά την ευημερία των κατοικίδιων ζώων. Δεδομένου ότι τα ζώα αναγνωρίζονται ως αισθανόμενα όντα τόσο από νομική όσο και από ηθική άποψη, η αδυναμία πολλών ιδιοκτητών κατοικίδιων ζώων να έχουν πρόσβαση στις απαραίτητες κτηνιατρικές υπηρεσίες δημιουργεί ανησυχίες σχετικά με τις ευρύτερες συνέπειες για την ευζωία των ζώων.

Ενώ ο πληθωρισμός και η τεχνολογική καινοτομία συμβάλλουν στην αύξηση του κόστους, πολλές χώρες αναγνωρίζουν ως κύρια αιτία την επιθετική ενοποίηση της αγοράς από λίγους εταιρικούς παράγοντες. Αυτοί οι κυρίαρχοι παράγοντες μειώνουν τον ανταγωνισμό και περιορίζουν τη διαφάνεια των τιμών, δημιουργώντας συνθήκες που θέτουν σε κίνδυνο την ευημερία των ζώων, καθώς αποθαρρύνουν την έγκαιρη και οικονομικά προσιτή πρόσβαση στη φροντίδα, ενώ ταυτόχρονα υπονομεύουν την ικανότητα των κτηνιάτρων να λειτουργούν ανεξάρτητα και ηθικά.

Ως απάντηση, έχουν εισαχθεί διάφορες νομοθετικές πρωτοβουλίες. Η Γερμανία εφαρμόζει ένα τιμολόγιο για τη ρύθμιση Η Ελλάδα έχει δημιουργήσει δημοτικές κτηνιατρικές υπηρεσίες για μειονεκτούσες ομάδες. Το Ηνωμένο Βασίλειο διερευνά αντιανταγωνιστικές πρακτικές στον τομέα. Οι Ηνωμένες Πολιτείες της Αμερικής έχουν προτείνει φορολογικές εκπτώσεις για κτηνιατρικά έξοδα. Αυτά τα παραδείγματα αντικατοπτρίζουν διαφορετικές προσεγγίσεις στην κατανομή των ευθυνών μεταξύ του κράτους, του επαγγέλματος και των ιδιοκτητών κατοικίδιων ζώων.

Για να εξασφαλιστεί η μακροπρόθεσμη πρόσβαση σε κτηνιατρική περίθαλψη και να τηρηθούν οι υποχρεώσεις για την ευημερία των ζώων, η έκθεση συνιστά μια πολυδιάστατη ρυθμιστική στρατηγική. Αυτή περιλαμβάνει διαφανή τιμολόγηση, αναλογική ρύθμιση των τελών, στοχευμένες δημόσιες υπηρεσίες και διασφαλίσεις κατά της υπερβολικής συγκέντρωσης της αγοράς. Αντί να βασιζόμαστε σε έναν μόνο παράγοντα, απαιτείται ένα μοντέλο κοινής ευθύνης για να διασφαλιστεί ότι τα οικονομικά εμπόδια δεν υπονομεύουν τις νομικές και ηθικές δεσμεύσεις για την προστασία της ευημερίας των ζώων.

Keywords: Νόμος για την προστασία των ζώων, κτηνιατρική περίθαλψη, ανταγωνισμός στην αγορά, δίκαιη τιμολόγηση, βιοηθική.

INTRODUCTION

As animals have become increasingly integrated into society and people's everyday lives, concerns related to animal welfare have received growing attention. Consequently, there have been developments in animal welfare legislation, both at the European Union (EU) level and within the national laws of its member states. However, certain aspects of animal welfare remain unregulated, raising important questions regarding the reach and limitations of the current legal framework.

Amid economic instability and rising prices, veterinary care for pet animals has become significantly more expensive. This trend has sparked political debate in several European countries and beyond, as recent statistics indicate that veterinary service providers have increased their prices significantly. Consequently, veterinarians report that pet owners, especially those belonging to vulnerable socio-economic groups, are delaying necessary care due to financial constraints (Pasteur et al., 2024).

Several factors contribute to this development. In countries with the highest veterinary costs, the market is often dominated by a few major corporations, limiting competition and restricting market access for smaller providers. Most countries lack legislation regulating veterinary service pricing, although some have introduced fee schedules and municipal veterinary care centers, as well as proposed tax deductions and further legislation preventing companies from raising the costs as of 2025.

This Report examines the legal and ethical challenges posed by rising veterinary costs in relation to animal welfare. It addresses relevant EU, international, and national legislation on animal welfare (I), ethical considerations (II), contributing factors and proposed legislative solutions to the rising costs of veterinary care (III) and concludes by presenting a conclusion & recommendations (IV).

I. CURRENT ANIMAL WELFARE LEGISLATION

1. Legislation in the EU

At the EU level, animal welfare is primarily regulated through Article 13 of the Treaty on the Functioning of the European Union (TFEU). This article obliges the Union and its Member States to pay full regard to the welfare requirements of animals, as sentient beings, when formulating and implementing Union policies in various sectors. Article 13 was introduced by the Treaty of Lisbon in 2007, elevating the overall legal status of animal welfare.[1] It imposes a binding obligation and holds normative value, influencing both legislative and judicial interpretations in animal welfare matters.

While all Member States have taken Article 13 into account when drafting national legislation, concerns remain about its uneven enforcement,[2] particularly its legal status when balancing other interests and whether it should be recognized as a general principle of EU law.[3]

[1] Before 2007, animal welfare was addressed in a Protocol on Protection and Welfare of Animals annexed to the Treaty of Amsterdam (1997), but it did not carry the same legally binding force.

[2] The policy initiative by the European Commission, *EU Strategy for the Protection and Welfare of animals 2012-2015,* aimed at improving the implementation and coherence of animal standards across member states by eliminating uneven enforcement.

[3] The article *Animal welfare in EU law: Scope and purpose of Article 13 of the treaty on the functioning of the European Union* published in 2024, discusses that the interpretation of the term "pay full regard to the welfare of animals" should give animal welfare

Although the term "animal welfare" is not defined in the treaties, it is generally understood to refer to a species-appropriate condition, a concept that is both scientifically grounded and normative. Article 13 is intended to cover all animal species, including companion animals.

Animal welfare is further addressed in Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health (the Animal Health Law). This regulation sets rules for preventing and controlling animal diseases to protect both public health and animal welfare. Although it primarily focuses on disease control in farm animals, it also includes provisions relevant to pet animals. Article 10 specifically addresses the responsibility for the health of kept animals, including their welfare. The regulation also sets minimum standards for veterinary practices in the Member States.

In December 2023, the European Commission introduced a Proposal for a Regulation of the European Parliament and of the Counsel on the welfare of dogs and cats and their traceability. It aims to establish minimum standards for the breeding, housing, and care of these animals. As of May 2025, this proposal is still under consideration and has not yet been adopted into EU law.

Although secondary EU legislation sets minimum animal welfare standards, mainly for farm and research animals, the welfare of pet animals is further regulated by international conventions and national laws.

2. International legislation and other regulations

Beyond EU legislation, international law further addresses the animal welfare of pets. In 1987, the Council of Europe introduced the European Convention for the Protection of Pet Animals, aiming to ensure pet welfare and promote responsible ownership. Articles 3 and 4 regulate the basic care and keeping of companion animals, requiring owners to ensure their animals' health and welfare, provide appropriate care, and avoid causing unnecessary pain, suffering, or distress. As of February 2025, the convention has been ratified by 27 countries, including 19 EU Member States. The convention set early welfare standards for pets, and its principles have also influenced the national laws of states that have not formally ratified it.

The World Organization for Animal Health (WOAH) is an intergovernmental body that publishes international standards to improve animal health, mainly through the establishment of high-quality national veterinary services. These standards are revised and adopted annually by its 180 member countries, including all EU states, which have committed to incorporating them into their national legislation and regulations.

In summary, EU and international legislation provide minimum guidelines for the welfare of pet animals. However, none of the instruments mentioned directly regulate access to affordable veterinary care services, leaving such matters to the discretion of individual Member States.

3. National legislation

Animal welfare legislation concerning pet animals is primarily governed by national law. Member States are free to enact legislation according to their socio-economic conditions, cultural norms, and religious beliefs, provided they comply with Article 13 TFEU, relevant EU regulations, and ratified international agreements. This flexibility has allowed countries to develop specific legal frameworks addressing various aspects of pet welfare, including access to veterinary care and pricing.

particular weight and importance, that Article 13 should be given general principle status, and that animal welfare should be given higher priority when balanced against other rights and interests.

All EU Member States have enacted some form of Animal Welfare Act, many of which exceed the minimum standards set by EU legislation. These laws share the common goal of protecting animals from unnecessary pain and suffering. Most national laws also require pet owners to provide necessary veterinary care without delay for injured or ill animals. Sanctions for non-compliance often include fines or imprisonment. Many countries have also adopted Veterinary Practice Acts, which regulate the professional duties and responsibilities of veterinarians and their services. Although veterinary care is recognized as essential to animal welfare, national laws generally say little about access to care in terms of fair pricing or affordability.

II. ETHICAL CONSIDERATIONS

1. From an Animal Welfare Point of View

One of the central questions highlighted by this Report is: Why should humans and society care about animal welfare and the provision of veterinary care? The ethical status of animals remains a topic of ongoing debate. While animals do not possess subjective rights from a legal standpoint, they are recognized as sentient beings under EU and international law. Some member states, such as Germany and Austria, also recognize animals as beings that are "not things", granting them protection under special statutes. However, in most countries, animals are still legally considered property, although with the added protection of animal welfare laws that mandate humane treatment and appropriate care.

Since animals are acknowledged as sentient, it is widely accepted that they can feel pain and therefore have an intrinsic interest in avoiding suffering. Accordingly, animal suffering should be prevented whenever possible, including suffering caused by untreated illness (Singer, 1975). Veterinary care is among the most effective means of alleviating pain, treating illness, and reducing suffering. From a utilitarian perspective, access to veterinary care is thus an essential component of animal welfare.

Humans have long domesticated, bred, and kept animals for companionship, entertainment, and labor. Today, pet animals are more integrated into human life and society than ever before. These developments suggest a moral responsibility on the part of pet owners, and a collective ethical duty of society, to meet animals' basic needs and prevent avoidable suffering, especially as animals are unable to advocate for themselves (Pasteur, 2024).

While some scholars argue that animals have basic moral rights, including the right to have their essential needs met, such as access to veterinary care, the ethical debate often centers on how to balance these responsibilities with economic constraints. Critics may argue that the duty to provide care lies solely with the owner, not the state or broader society. From a libertarian perspective, one might oppose that market-driven solutions are preferable, and that subsidizing or regulating veterinary care would infringe on personal freedom and autonomy (Nozick, 1974). Conversely, others argue that market values do not belong in every sphere of life, and that moral limits should be placed on the free market, which could apply to veterinary care from an ethical and animal welfare standpoint (Sandel, 2012).

2. The Human-Animal Bond

Another key ethical dimension of veterinary care access is the human-animal bond. Numerous studies have shown that this bond benefits both animals and humans.[4] Given its importance in modern society, the lack of access

[4] Research on the human–animal bond consistently shows positive effects on both human and animal well-being. Studies have linked pet ownership to reduced stress, improved mental health, and lower blood pressure in humans, while animals benefit from increased social interaction, stimulation, and care (Friedmann and Son, 2009).

to veterinary care negatively impacts both human and non-human members of communities (Blackwell, 2023). The current economic climate has made it more difficult for many pet owners, especially those from socio-economically vulnerable groups, to afford veterinary care. Inflation and rising veterinary costs have contributed to these challenges. Research shows that some owners avoid purchasing pet insurance or are forced to cut other essential expenses to afford veterinary treatment (Reader and Summers, 2024). As animal welfare laws evolve at both the EU and national levels, pet owners face increased legal obligations to meet the needs of their animals. Failure to do so may lead to legal consequences. Therefore, access to affordable veterinary care is not only a matter of animal welfare but also a pressing socio-economic concern.

III. CAUSING FACTORS AND PROPOSED LEGISLATIVE SOULTIONS TO THE RISING COSTS OF VETERINARY CARE

1. Causing Factors

The rising costs of veterinary care can be attributed to several interrelated factors. One of the most significant is inflation, which has generally driven up the cost of goods and services. However, the cost of veterinary care has increased at a rate significantly higher than that of many other services, outpacing overall inflation in several countries.[5]

This disproportionate increase is largely attributed to structural distortions within the veterinary sector, which have enabled large corporate actors to raise prices for consumers. This trend is particularly evident in countries where veterinary expenses have risen drastically. Other contributing factors include a lack of price transparency, and the increasing costs associated with advanced medical technologies and equipment.

These developments have sparked political debate, not only from an animal welfare perspective but also in terms of market fairness and competition. In response, several countries have implemented, or are considering, legislative interventions aimed at safeguarding animal welfare while keeping veterinary services accessible and affordable for pet owners. The following section outlines existing and proposed legislative solutions intended to address these challenges and improve access to veterinary care.

2. Legislative Solutions

a) The Fee Schedule in Germany

Germany is currently the only country that provides concrete legislation regulating the pricing of veterinary care services. Article 12 of the Federal Veterinary Practicing Act (BTÄO) authorizes the Federal Government to regulate

[5] A 2024 study published in *Frontiers in Veterinary Science* reports a 25% increase in the cost of veterinary care services in Sweden since 2023 – an increase that exceeds the general Consumer Price Index (CPI). Comparable trends have been observed in Denmark and Norway. According to *Euromonitor International*, veterinary care prices in Greece rose in 2022 as a result of high inflation. In the United Kingdom, the *Competition and Markets Authority (CMA)* has documented a 50% increase in veterinary costs between 2015 and 2023, also surpassing the general rate of inflation.

veterinary service fees, including the prices and price ranges for medicinal products used by veterinarians, within a schedule of fees. The law further states that the legitimate interests of both veterinarians and those obligated to pay the fees must be taken into account.

The government-mandated Fee Schedule for Veterinarians (*Gebührenordnung für Tierärzte*, GOT) was originally issued in 1940 based on Article 12 and was comprehensively revised in 1999 to its current form. The schedule sets a fee range for veterinary services from at least one to a maximum of three times the set base fee, depending on the nature and complexity of the service provided. Its primary aim is to ensure standardized and transparent charges that maintain fairness for both veterinarians and pet owners, while also preserving access to affordable care within a regulated framework.

In May 2022, the German Federal Ministry of Food and Agriculture presented a draft bill proposing amendments to the GOT, arguing that it was outdated and no longer reflected current veterinary practice or economic conditions. The proposed changes were based on recent research and consultations with the Federal Chamber of Veterinarians, which included surveys and expert interviews analyzing the costs and structure of veterinary clinics.[6] The revised GOT included increased basic fees, provisions allowing veterinarians to charge above the standard rate in certain circumstances, and mandatory travel fees for home visits, among other changes.

The draft bill asserts that the amendment is compliant with applicable EU law. In accordance with Directive (EU) 2018/958 on conducting a proportionality assessment before adopting new regulations for professions, an evaluation was carried out. The conclusion was that the revised fee categories and adjustments were proportionate, being evidence-based, transparently derived, and mindful of economic, structural, and professional considerations. The bill also addressed regulatory impacts, noting that veterinary services would become more expensive. Nonetheless, it argued that the willingness to seek veterinary care would likely remain high due to existing animal welfare obligations. From a sustainability perspective, the amendment was also seen as contributing to economic growth and improved animal health, aligning with sustainable development goals.

In stakeholder consultations, the German Animal Welfare Association emphasized the importance of fair compensation for veterinarians in maintaining a nationwide care network and veterinary infrastructure. However, it expressed concern that fee increases could negatively impact animal shelters, welfare organizations, and economically vulnerable pet owners. While financial improvements for veterinarians were deemed necessary, the Association stressed that animal welfare must not suffer as a result.

Similarly, the Federal Office for Technical and Scientific Affairs, along with the Association of Independent Small Animal Clinics, welcomed the amendments, citing severe staffing and compensation issues in the

[6] From the collected data in the report *Examination of the Financial and Structural Impacts Regarding the Appropriateness of the Fee Rates of the Veterinary Fee Schedule (GOT)*, the average cost per treatment minute was calculated at €2.25. This was used to determine revised fees, considering time and service specific data.

profession. However, they also argued that many service fees remain too low and that the amendment represented a missed opportunity to secure the long-term future of the veterinary profession through a truly modern and sustainable fee structure.

Following the enactment of the legislation, the Scientific Services of the Bundestag published a 2024 report summarizing the status of the GOT.[7] The report noted concerns that pet owners' interests may have been underrepresented during the amendment process, particularly in light of the sharp fee increases. Questions were also raised as to whether the changes had achieved their goal of ensuring fair pricing from the perspective of pet owners.[8] Although the GOT has historically faced criticism from the EU for restricting competition in a liberalized market,[9] German legislators maintain that the 2022 amendments align with applicable EU directives.

b) Government Funded Veterinary Care in Greece

A few EU countries, including Greece, have introduced legislative initiatives that provide free veterinary care through municipal or public programs. These initiatives primarily target socio-economically vulnerable pet owners and aim to address the issue of stray animal populations.

Greece's main legislation governing animal welfare is the Animal Welfare Act 4830/2021 (the Act), which came into effect in September 2021. The purpose of the Act is to protect domestic animals and promote responsible pet ownership. A key feature of the Act is the establishment of a new funding framework known as "Argos", which allocates funding to municipalities and fosters collaboration with animal welfare organizations. The program is set to receive €40 million for the construction and equipping of shelters and veterinary clinics.[10]

Article 10 of the Act mandates that municipalities establish and operate municipal veterinary clinics and animal shelters. These measures are part of a national strategy to manage and care for both stray animals and pets. This marks a significant shift from previous legislation, which placed full responsibility on pet owners and veterinarians for implementing the law. Under the new framework, municipalities may fulfill these duties individually, in cooperation with other municipalities, or in partnership with registered animal welfare organizations.

In addition, Article 4(13) of the Act recognizes pet owners belonging to vulnerable or socially disadvantaged groups. It requires

[7] German Bundestag, *Legal Questions Regarding the Veterinary Fee Schedule (GOT)*, Scientific Services Report WD 8 – 3000 – 066/24, September 2024.

[8] In 2023, the Association of German Animal Keepers (VDTH) submitted a petition to amend the GOT, based on that treatment costs for pet owners have increased dramatically driving pet owners into debt and endangering animal welfare, since animals are being treated inadequately or too late, surrendered to animal shelters or abandoned.

[9] From a historical and political point of view, GOT is over 80 years old with aspects such as inflation and World War II being catalysts for it. It has also historically received criticism from the EU regarding the Fee Schedule being anti-competitive in the light of 2006/123/EU Directive on Services in the Internal Market (Bartkowiak, 2017).

[10] Available at: https://www.ypes.gr

municipalities to provide free services such as sterilization and vaccination for animals owned by individuals in these groups. Eligible individuals include people with disabilities, families with multiple children, single-parent households, and unemployed people receiving the minimum guaranteed income. This provision aims to promote responsible pet ownership and prevent the abandonment of animals due to financial hardship.

The "Argos" program has been widely praised by animal welfare organizations and the public as a progressive step toward reducing irresponsible pet ownership and improving animal welfare. However, some stakeholders have described the program as overly ambitious and difficult to implement in practice. Concerns have been raised regarding the lack of adequate resources, training, and expertise among local authorities, particularly within municipalities tasked with enforcing the law. Some pet owners have also criticized the program for the added financial burden associated with mandatory sterilization and registration, despite the government's recent decision to reduce overall service fees (Siettou et al., 2024).

Although the Act is considered one of the most progressive animal welfare laws in the EU, its practical effectiveness remains uncertain. A post-implementation review is expected in 2026, which will provide a clearer picture of the law's impact and long-term feasibility.

c) Veterinary Market Investigations in the United Kingdom

The trend of rising veterinary costs is not limited to the EU. In May 2024, the United Kingdom's Competition and Markets Authority (CMA) launched an in-depth market investigation into veterinary services for household pets[11], in response to the growing costs that have sparked widespread concern among pet owners and raised questions about the impact on animal welfare. A key focus of the investigation is the lack of market competition and pricing transparency, which are believed to be driving disproportionately high profit margins.

The investigation has identified several major concerns in the United Kingdoms' £5 billion pet care industry. According to CMA working papers, the most pressing issues include the consolidation of formerly independent veterinary practices by a few large corporate groups and the lack of transparent pricing. In recent years, the United Kingdom veterinary sector has experienced significant consolidation, with nearly 60% of first-opinion veterinary practices now owned by the six largest corporate veterinary groups[12]. This is a substantial increase from 2013, when only 10% of practices were corporately owned. These developments have raised concerns about potential breaches of national competition law, which is designed to ensure markets remain sufficiently competitive to protect fair pricing, innovation, and consumer choice.

Legal scholars have pointed to the role of private equity-backed corporations as a key driver of these trends. These corporations

[11] Available at: https://www.gov.uk/cma-cases/veterinary-services-market-for-pets-review

[12] IVC Evidensia (the largest corporation, with a share of approximately 22 %), Pets at Home, CVS, Linnaeus, Medivet, and VetPartners. Of these, IVC, Medivet and VetPartners are each owned or financially backed by private equity groups.

provide capital, strategic oversight, and operational support to acquire and integrate smaller practices, capitalizing on the fragmented and underfunded nature of the veterinary market, especially in rural areas. Many of these businesses employ "roll-up" strategies, acquiring independent clinics while retaining their original branding. This can obscure corporate ownership and maintain consumer trust, but it also raises concerns about misleading impressions of market diversity and competition. While such strategies may improve operational efficiency, critics argue they often prioritize short-term profits, reduce service quality, and create barriers to transparency (Reader and Summers, 2024).

The CMA has the authority to implement legally binding remedies if it concludes that competition is being hindered. Although the United Kingdom has a voluntary merger notification system, the CMA maintains a proactive strategy for identifying and investigating problematic acquisitions. Since the launch of the market investigation, four mergers have been reviewed, all of which were found to pose a realistic risk of substantially lessening competition. Potential remedies at the CMA's disposal include requiring businesses to disclose specific information to consumers, setting maximum fees for veterinary services, or ordering the divestment of businesses or assets.

As of May 2025, several major veterinary corporations have formally responded to the ongoing investigation. While these companies urge the CMA to consider the wider industry and societal changes that are shaping the veterinary sector, such as technological advances, evolving medical knowledge, and changing societal expectations regarding pet care, they appear to be preemptively aligning with anticipated regulatory recommendations. Notably, many practices have begun publishing more comprehensive pricing information online, which some academics interpret as a strategic move to avoid stricter regulatory measures (Reader and Summers, 2025). The CMA is expected to issue a provisional decision in summer 2025, with a final report due in November. The findings could lead to significant reforms in the veterinary sector, including new regulatory frameworks aimed at improving competition and transparency.

Concerns about the corporatization of veterinary medicine are not unique to the United Kingdom.[13] Similar trends are observable across Europe, where several multinational corporations operate by acquiring and consolidating private practices. While the EU does not currently maintain a unified legal framework regulating veterinary corporate ownership, some member states have implemented national laws to restrict non-veterinary ownership. For example, in France, veterinary businesses must be majority-owned by licensed veterinarians to safeguard professional independence and avoid conflicts of interest. In Austria, limited non-veterinarian ownership is permitted, provided veterinarians retain decisive control. In contrast, countries like the United Kingdom and Sweden currently lack such regulations, allowing for broad non-veterinary ownership (Diana et al., 2025).

Professional associations across Europe have raised concerns about the potential conflict of interest posed by corporatization, emphasizing the need to protect veterinary independence and uphold animal welfare. Additionally, the European Commission has addressed competition issues related to vertical integration in the veterinary sector, calling for closer scrutiny of mergers and acquisitions that may harm market competition.[14]

[13] In 2022/2023 around 16% of veterinarians worked in corporate practices across 37 European countries, with the highest numbers of veterinarians working in corporate practices are seen in the United Kingdom (44%), Sweden (34%), and Norway (27%) (VetSurvey, 2023).

[14] The European Commission cleared Mars, Inc. acquisition of AniCura subject to an in-depth review

While much of the debate focuses on market dynamics and affordability, animal welfare remains a central concern. Although there are currently no dedicated studies assessing the impact of corporatization on animal welfare, it is suggested that the effects may be twofold. On one hand, corporate ownership may enable greater investment in advanced treatments and technologies; on the other hand, rising costs could deter pet owners from seeking necessary care. Some academics argue that the current market structure, particularly where cost pressures meet aggressive consolidation, puts animal welfare at risk (Diana et al., 2025; Reader and Summers, 2024).

d) Proposed Bill for Tax Relieves in the United States of America

The trend of rising veterinary care costs is also evident outside of Europe. In the United States of America (USA), the cost of urban veterinary services has increased by nearly 60% over the past decade and rose by 7.9% between February 2023 and February 2024.[15] This significant increase has led many pet owners to delay or forgo necessary veterinary care for their animals.

In response, a bipartisan bill titled The People and Animals Well-being Act of 2024 (PAW Act, H.R. 9508) has been introduced in the United States House of Representatives. The bill seeks to improve the affordability of veterinary care and pet health insurance by amending the Internal Revenue Code of 1986, the federal tax law, to classify certain veterinary expenses for pets and service animals as qualified medical care expenses under tax-advantaged accounts.

The PAW Act proposes to allow pet owners to use Health Savings Accounts (HSAs) and Flexible Spending Accounts (FSAs) to cover up to $1,000 annually for veterinary care or pet health insurance premiums. For individuals who rely on service animals, particularly those assisting with physical or mental disabilities, the bill would permit unlimited veterinary care expenses to be covered through these accounts. This would effectively exempt such expenses from income tax, thereby reducing taxable income and alleviating the financial burden of veterinary costs.

The bill has received public endorsement from key stakeholders, including the American Veterinary Medical Association (AVMA) and the Human Animal Bond Research Institute (HABRI). Both organizations emphasize its potential to improve access to veterinary care and strengthen the human-animal bond. As of May 2025, the PAW Act remains in the early stages of the legislative process and has been referred to the House Committee on Ways and Means. It is still awaiting a formal cost estimate and additional input from relevant stakeholders.

IV. CONCLUSION & RECOMMENDATIONS

Based on the presentation above, several initial conclusions can be drawn. The issue of rising veterinary costs is observable across multiple countries, yet the legislative responses to this problem differ significantly, particularly regarding which actors are expected to bear the financial responsibility of the solution. In Germany, the Fee Schedule and the proposed market regulations in the United Kingdom primarily place obligations on veterinary businesses and corporate entities. In contrast, the establishment of municipal veterinary clinics in Greece and proposed tax relief measures in the USA shift the responsibility toward the state, aiming to reduce the financial burden on pet owners. In jurisdictions where no regulatory

of competition concerns arising from vertical integration, particularly the risk of input and customer foreclosure in the pet healthcare and pet food markets (Case M.9019 – Mars/BVA, Commission Decision of 9 November 2018).

[15] Bureau of Labor Statistics. Available at: https://www.bls.gov/news.release/cpi.t02.htm

interventions have been implemented to control pricing or ensure access to affordable veterinary care, market forces are left to determine costs, resulting in pet owners shouldering the full economic burden.

While access to affordable veterinary care is an issue of growing concern from an animal welfare perspective, the political discourse is largely driven by considerations of market dynamics and the financial capacity of pet owners, often placing animal welfare as a secondary concern. This raises the question of whether legislation in other areas, such as competition law and tax law, could have a positive indirect effect on animal welfare, even if this was not the primary intention of the legislators. Although the proposed measures do not stem directly from an animal welfare perspective, they may nonetheless contribute to improved welfare for pet animals by making veterinary care more financially accessible.

The central issue addressed in this report is the conflict between animal welfare and the free market dynamics of veterinary services. Economic considerations are consistently present in discussions on animal welfare, requiring a careful balance between cost factors and ethical responsibilities. The following part presents recommendations that may prove valuable in developing future regulations aimed at ensuring fair pricing and accessible veterinary care services.

1. Current legislative measures tend to place the financial burden exclusively on a single actor within the market, whether it be the veterinary sector, the state, or the pet owner. A more multi-faceted approach would involve distributing this responsibility across all three parties through a combination of targeted legislative solutions. By doing so, the overall financial burden would be shared more equitably, reducing the pressure on any one actor and fostering a more sustainable and fair system for funding veterinary care.

2. Introducing the possibility of government-mandated exceptions to free-market regulations for basic veterinary care could help ensure compliance with animal welfare laws. One potential approach is the implementation of a standardized fee schedule that guarantees fair compensation for veterinarians while preventing excessive profit margins. Government intervention should be carefully balanced and proportionate to avoid anti-competitive effects, while still allowing the veterinary sector to profit and invest in advanced treatments and technologies, ultimately benefiting animal welfare.

3. By promoting national legislative measures that enhance price transparency and ensure fair competition, pet owners would gain greater oversight of veterinary pricing and market concentration. This would make it more difficult for large corporations, particularly those backed by private equity, to undermine the veterinary sector, thereby helping to preserve veterinarians' independence and prevent profit-driven practices from compromising animal care. Enhancing market competition regulation could subsequently contribute to making veterinary care more affordable.

4. To support socio-economically vulnerable groups, municipal clinics and tax reductions represent potential solutions. However, these measures often face practical implementation challenges and may lack cost-effectiveness when executed on a greater scale. It can be argued that such approaches primarily address the symptoms of a dysfunctional system rather than its root causes. Consequently, legislative efforts would likely be more effective if directed toward addressing the underlying factors driving the issue.

References

Bartkowiak, A. (2017): Success Model or Outdated Concept? Origin, Development and Future of the Fee Schedule for Veterinarians in Germany (Erfolgsgarant oder Auslaufmodell? Entstehung, Entwicklung und Zukunft der Gebührenordnung für Tierärzte in Deutschland), *Cuvillier Verlag*, 2017, p. 158-159.

Blackwell, M. J., & O'Reilly, A. (2023). Access to veterinary care–a national family crisis and case for one health. *Advances in Small Animal Care*, 4(1), 145-157. https://doi.org/10.1016/j.yasa.2023.05.003

Diana, A., Mickov, D., van Dobbenburgh, R., Jansen, W., Sternberg Lewerin, S., Neumann, S.,

& De Briyne, N. (2025, March). Quo Vadis: Is Corporatisation Reshaping Companion Animal Veterinary Care in Europe? In *Pets* (Vol. 2, No. 1, p. 15). MDPI.

Egenvall, A., Höglund, O., Hoffman, Valle., P., Andersen, P., Lönnell, C., Byström, A. and Bonnett, B. (2024): Prices for veterinary care of dogs, cats and horses in selected countries in Europe. *Front. Vet. Sci*., 18 July 2024. https://doi.org/10.3389/fvets.2024.1403483

Friedmann, E., & Son, H. (2009). The human–companion animal bond: How humans' benefit. Veterinary Clinics of North America: *Small Animal Practice*, 39(2), 293-326. https://doi.org/10.1016/j.cvsm.2008.10.015

Loeb, J. (2025): Vet market pre-empting CMA remedies. *Veterinary Record*, Volume 196 Issue 5, p. 165-165. https://doi-org.ezp.sub.su.se/10.1002/vetr.5274

Nozick, R. (1974): Anarchy, state, and utopia. Basic Books. Chicago / Turabian.

Pasteur, K., Diana, A., Yatcilla, JK., Barnard, S. and Croney, CC. (2024): Access to veterinary care: evaluating working definitions, barriers, and implications for animal welfare. *Front. Vet. Sci.* 11:1335410.

Reader, D., Summer, S. (2024): Paws for Thought: Putting UK Vet Acquisitions on a Tightened Leash. *CPI Antitrust Chronicle*, *2024*(Jun II).

Sandel, M. J. (2012): What money can't buy: The moral limits of markets. Farrar, Straus and Giroux.

Siettou, C., Theodoropoulou, E., Siettou, A.S. (2024): An Overview of Greece's Newly Established Progressive Stray Dog Management Laws. *Pets*, 2(1). https://doi.org/10.3390/pets2010001

Singer, P. (1975): Animal Liberation: A New Ethics for Our Treatment of Animals. New York: New York Review.

Stucki, S. (2020): Towards a theory of legal animal rights: Simple and fundamental rights. *Oxford Journal of Legal Studies*, 40(3), 533-560. https://doi.org/10.1093/ojls/gqaa007

Vapnek, J., & Purnhagen, K. (2024): Animal welfare in EU law: Scope and purpose of Article 13 of the treaty on the functioning of the European Union, *European Law Review*, 49(2), 188–199. https://search.informit.org/doi/10.3316/informit.T20241218000096001310282 91

Ελληνική Δημοκρατία
Εθνική Επιτροπή
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ΙΝΣΤΙΤΟΥΤΟ ΠΛΗΡΟΦΟΡΙΚΗΣ & ΤΗΛΕΠΙΚΟΙΝΩΝΙΩΝ

ΒΙΟΗΘΙΚΑ
Ηλεκτρονικό Περιοδικό

Ανασκοπήσεις - Reviews

AI and Democracy: Concerns, scenarios and ethical dilemmas

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Abstract

If Artificial Intelligence envisages the 4.0 Industrial Revolution and if Technoethics is the multi-disciplinary field that sounds out and discerns the ways our value systems are impacted in the light new technologies, this Article seeks to bring forward opinions voiced on the future of human society, politics and democracy. Is the excessive deployment of AI in both private and public sphere capable of affecting our way of thinking, judging, acting, reacting, making (or delegating) decisions and participating in the res publica? Capitalizing on the field of neuroethics and political science we classify the procedures of human political decision-making, while bringing forward the opinions of techno-optimist and techno-pessimist scholars. Line of arguments ranging from bona fide usage of AI, ethical policy making, enhanced democratic representation down to solutionism and democratic perils of Algorithmic Decision-Making, Echo Chambers, AI biases, and gaps in Accountability, Responsibility, Transparency and Explanation will be presented as a bibliography overview. In the Discussion area paradigms and ethical dilemmas will be outlined for the interest of future research.

Keywords: AI, neuroethics, democracy, political decision-making, governance.

ΤΝ και Δημοκρατία: Προβληματισμοί, σενάρια και ηθικά διλήμματα

Αικατερίνη Σαμπαθιανάκη[1,2]

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[2] Ασκούμενη, Εθνική Επιτροπή Βιοηθικής και Τεχνοηθικής, Ελλάδα.

Περίληψη

Έστω ότι η Τεχνητή Νοημοσύνη μετουσιώνει την 4.0 Βιομηχανική Επανάσταση και έστω ότι η Τεχνοηθική αποτελεί τον διαθεματικό εκείνο κλάδο που αφουγκράζεται και διερευνά τον βαθμό στον οποίο τα αξιακά μας συστήματα επηρεάζονται υπό το φως των νέων τεχνολογιών, το παρόν άρθρο φέρνει στο προσκήνιο απόψεις επιστημόνων και ερευνητών αναφορικά με το μέλλον της ανθρώπινης κοινωνίας, την πολιτική και τη δημοκρατία. Είναι ικανή η υπερβολική ανάπτυξη της ΤΝ τόσο στην ιδιωτική όσο και στη δημόσια σφαίρα να επηρεάσει τον τρόπο με τον οποίο σκεφτόμαστε, κρίνουμε, ενεργούμε, αντιδρούμε, λαμβάνουμε (ή αναθέτουμε) αποφάσεις και συμμετέχουμε στα κοινά; Αξιοποιώντας το πεδίο της νευροηθικής και της πολιτικής επιστήμης, ταξινομούμε τις διαδικασίες της λήψης πολιτικών αποφάσεων, ενώ προβάλλουμε τις απόψεις τεχνο-αισιόδοξων και τεχνο-πεσιμιστών μελετητών. Υπό τη δομή βιβλιογραφικής επισκόπησης, παρουσιάζονται επιχειρήματα που κυμαίνονται από την καλόπιστη χρήση της ΤΝ, τον λυσιλογισμό [solutionism], την ενισχυμένη δημοκρατική εκπροσώπηση, έως τους δημοκρατικούς κινδύνους της αλγοριθμικής λήψης αποφάσεων [ADM], τους θαλάμους αντήχησης [echo chambers], τις προκαταλήψεις της ΤΝ και τα κενά στη Λογοδοσία, την Ευθύνη, τη Διαφάνεια και την Εξήγηση. Στο τελευταίο μέρος παρουσιάζονται προτάσεις και ηθικά διλήμματα για μελλοντική έρευνα και δημόσιο διάλογο.

Λέξεις κλειδιά: ΤΝ, νευροηθική, δημοκρατία, λήψη πολιτικών αποφάσεων, διακυβέρνηση.

Introduction and methodology

The 4.0 Industrial Revolution mirrored in Artificial Intelligence [henceforth AI] constitutes an undeniable here-and-now reality, urging modern societies to revisit their standards, value systems and contemplate new governance models to achieve human-machines equilibrium. Are we standing on transformative crossroads where AI takes over democracy giving birth to authoritarian-like regime, or is it safe to say that Democracy and AI are set out on a journey of symbiotic co-existence?

Current concerns of academia are rooted in political philosophy, ethics of technology, governance models, neuroethics and decision-making typology, and the role of AI-induced settings in political discourse and public sphere. New concepts such as Algorithmic Decision-Making, Hybrid Media Systems, Echo Chambers, Bubble Effect and AI biases, Big Data abusive usage, deepfakes and their impact on our citizenship-building procedure are tabled by the techno-pessimist front. Techno-optimist scholars stress the positive role of AI systems in participatory democracy, ethical policymaking, administration and bureaucratic settings.

This is a Technoethics oriented Literature Review intended to discern the latest opinions on *hows* and *ifs* AI algorithms, social media platforms and internet-based systems affect the democratic foundations by grooming public opinion, free will political decision making and civic identity.

Methodologically, we combined narrative and thematic approaches, filtering academic work from political scientists, neuroscientists, behavioral economists, technology institutes and democracy watchdogs to depict both techno-optimist and techno-pessimist views on the future of democracies, while bringing forward various scenarios and recommendations. The Discussion session highlights ethical dilemmas and philosophical questions for future research.

While effort was put to ensure coherence and well-structured pace, this paper inevitably falls short of numerous angles, since this is a dynamically growing field evolving countless experts with fresh research emerging as we write. Given its inherently multidisciplinary nature, technoethics has open-end cognitive and conceptual boundaries, yet to be mapped and delimited.

Neuroethics and Political Decision-Making

Political Decision-Making in Human Societies

If free will of free people is the buttress of democracy, discerning the cognitive basis of political decision-making combined with legitimacy and free elections is primordial. The mechanism of human choice is shaped by individualized contexts, and personal, social and cultural determinations often acting as perception systems, biases and brain heuristics.[1] Thaler and Sunstein reiterate the typology of Kahneman and Tversky (1983) pinpointing the common rules of thumbs governing human judgement and decisions: the heuristics of Anchoring, Availability, and Representation.[2] These modalities function as mental shortcuts and affect our judgements and by extension our political reasoning, especially in democracies where legitimacy is founded on the citi-

[1] Braun R. Artificial Intelligence: Socio-Political Challenges of Delegating Human Decision-Making to Machines. Institute for Advanced Studies (IHS), Vienna, 2019, p.13.

[2] Thaler, RH, Sunstein C R. Nudge: Improving Decisions About Health, Wealth, and Happiness, Revised & Expanded edition. Penguin Books, New York, 2009.

zens being the main source of mandate. Here is a cyclic effect: political decisions and outputs are interlinked with citizens and turn back to them in the form of views and preferences.[3] So, effective governance means inputs (e.g. citizens' preferences) been translated into outputs (policies).[4] Yet another factor of democratic discourse is called "hermeneutic element" where citizens should actively and critically interpret information instead of accumulating bulks of data, whereas liberal democracies are often depicted as "a social technology" designated to manage societal complexity.[5]

Neuroethics, Free-Will and Decision-making

Neuroscientist Michael Gazzaniga termed neuroethics as a field that comments on life by means of neuroscience embedded methodology.[6] Issues of perceptions, memory, consciousness, free will and decision-making fall in this scope. Key areas of neuroethics also cover brain privacy and informed consent thus often aligning the field with medical and forensic domains. It also delimits cognitive processes such as memory distortion, particularly the phenomenon of false memories, biases and perception systems. Our brain tends to reshape memories via a "fit-to-adjust" mechanism to fit the (desired) result. The construction of perception systems is also described by neuroethics as an effort of the human brain to "release capacity" been physically unable to hold on to every information. This property is highly exploitable by the (social) media ecosystem which tends to deploy algorithms to "plant" memories, boost emotional addiction and shape perception systems. Damasio's research reinforces this perception by asserting that emotions are the founding stone of reason and logic.[7]

Free will and the cerebral path to moral choices is yet another contribution of neuroethics; it is argued that moral judgements follow a similar cerebral path to other brain activities: ethical dilemmas are brought forward, filtered and examined and final choices emerge (almost automatically) mainly at the anterior cingulate cortex (ACC) where decisions translate into actions paving the way for "free will" property. Some neuroscientists however, put the notion of "free will" to test. Vilayanur Ramachandran, gives an interesting take on Libet's results[8] arguing that decisions are constantly processed by the nonconscious parts of

[3] Scharpf FW, Governing in Europe: effective and democratic? Oxford University Press, 1999.
[4] Klingemann HD, Hofferbert R, Budge I. Parties, Policies, And Democracy (Theoretical Lenses on Public Policy). Western Press, 1994, p.8.
[5] König PD, Wenzelburger G. Opportunity for renewal or disruptive force? How artificial intelligence alters democratic politics. Government Information Quarterly, 2020, 3. https://doi.org/10.1016/j.giq.2020.101489.
[6] Gazzaniga M. The Ethical Brain. Dana Press, Washington, DC, 2005.
[7] Ντινόπουλος Θ. Νευροηθική. Επιστημονικές Εκδόσεις Παρισιάνου, Αθήνα, 2008.
[8] For a detailed report of Libet's experiment see Παπαδόπουλος Β. Νευροηθική: Ηθική και νομική ευθύνη. Το πρόβλημα της ελεύθερης βούλησης υπό το φως των ευρημάτων της νευροεπιστήμης, 2016, p.33-35. https://elocus.lib.uoc.gr/dlib/b/9/5/metadata-dlib-1536919653-758322-19292.tkl.
or: https://www.youtube.com/watch?v=6VZqho-8iJY

the neocortex and solutions/ actions then ascend like *bubbles* to our conscious awareness. Ramachandran introduces the notion of "free won't" - i.e., the power to reject solutions proposed by the nonconscious parts of the neocortex.[9]

The determinism and reductivism theories aside, human behavior results from the interaction of brain functions and is affected by social and cultural conditions. Later paragraphs examine how AI and Algorithimic Decision-Making (ADM) run the risk of neutralizing "social accountability" in political decisions.

AI & Democracy: The Techno-optimist perspective

The social benefits associated with new technological advancements are undeniable when (and if) such apparatuses get ethically designed, based on Research Integrity [RI] and Research Security [RS][10] standardization and aligned with the societal core values. If algorithmic properties are deployed considering public benefit, there are some interesting gains for democracies and citizens: direct cognitive upskilling, innovation, research, investments, new jobs and opportunities, let alone a philosophical and ontological shift. Democracy could use AI to help it become more resilient against authoritarian arrhythmia, blind spots and slippery slopes.

AI Boosting civic representation

By leveraging social media and algorithmic fast-track turnaround of world's news and exchange of opinions, democratic representation and informational autonomy of citizens is improved, thus improving political engagement and healthier decision-making.[11] AI applications lend a hand to disabled persons, remote residents and politically detached citizens, allowing them access to fairer information, transparent political views and more qualitative content engagement.

Paulo Savaget, Tulio Chiarini and Steve Evans argue that AI systems improve civic participation in democracy via open-data and online open-source repositories,[12] while others adds that higher engagement mitigates the citizen's dependency on political representatives' elites.[13][14]

AI enhancing political discourse and citizen's DM

Various scholars argue that if properly trained and ethically designed, AI can boost the "democratic potential" by state-of-art con-

[9] Ramachandran VS, Blakeslee S. Phantoms in the Brain: Probing the Mysteries of the Human Mind. William Morrow and Company, HarperCollins, 1999.

[10] Mollaki V, Ziouvelou X, Giouvanopoulou K, Karkaletsis V. Promoting Research Security through Research Ethics and Integrity practices: recommendations for policy actions, 2025. https://doi.org/10.5281/zenodo.15696984.

[11] Ünver HA. Artificial Intelligence, Authoritarianism and the Future of Political Systems. EDAM, Oxford CTGA & Kadir Has University, 2018.

[12] Savaget P, Chiarini T, Evans S. Empowering political participation through AI. Science and Public Policy, 2019, 46(3):369–380.

[13] Pateman C. Participation and Democratic Theory, Cambridge University Press, 1970.

[14] MacPherson CB. The Life and Times of Liberal Democracy, Oxford University Press, 2012.

tent moderation and mitigation of algorithmic biases.[15] It could also avert hate speech, improve political campaigns, filter deepfakes, social bots and other harmful agents, thus allowing human actors to interact ethically and freely. AI induced social media could uphold the political ethos, strengthen democracy, foster rule of law, fight oppression and discrimination and enhance political mobilization, introducing a new era for human rights movements and other "normative shifts with profound political impacts".[16] The same views are echoed by Sgueo[17] while Battista suggests ethical AI upgrades the efficiency of political decisions.[18]

Policy, regulation and international cooperation

In terms of free and democratic elections, AI induced settings could boost transparency and accountability and truly back up democracies.[19] AI systems and Big Data could yield impressive democratic gains for electorates when policymakers deploy them to ameliorate public administration and e-government, let alone mitigate corruption. Big Data serves democracies when ethically applied in the healthcare, justice or security domains.[20]

Sounding out the alarmist voices, governments, unions and organizations around the globe join forces to prioritize cyber security and AI ethics by establishing Ethics Committees,[21] Councils and by drafting regulations, codes and instruments (soft and hard law) to fortify liberal values, democracies and humanity's set of moral principles from any technological wrongdoing in the future. In parallel,

[15] Wojcieszak M, Thakur A, Ferreira Gonçalves JF, Casas A, Menchen-Trevino E., Boon, M. Can AI Enhance People's Support for Online Moderation and Their Openness to Dissimilar Political Views? Journal of Computer-Mediated Communication, 2021, 26: 223–243. https://academic.oup.com/jcmc/article/26/4/223/6298304

[16] Thiele LP. Politics of Technology-Specialty Grand Challenge. Front. Polit.Sci., 2020, 2.

[17] Sgueo G. BRIEFING (Re-)thinking democracy Digital democracy Is the future of civic engagement online? EPRS | European Parliamentary Research Service, 2020. https://www.europarl.europa.eu/RegData/etudes/BRIE/2020/646161/EPRS_BRI%282020%2964616 1_EN.pdf. In: Jafarova LA. Political institutions in times of AI, and Ethical Aspects of the Digitalization in Politics. SCIENDO: Polish Political Science Review, 2014, p. 8.

[18] Battista D. Political communication in the age of artificial intelligence: an overview of deepfakes and their implications. Society Register, 2024, 8(2).

[19] Klievink B, Romijn BJ, Cunningham S, de Bruijn H. Big data in the public sector: uncertainties and readiness. Information Systems Frontiers, 2017, 19: 267–283.

[20] Höchtl J, Parycek P, Schöllhammer R. Big data in the policy cycle: policy decision making in the digital era. Journal of Organizational Computing and Electronic Commerce, 2016, 26:147–169. https://doi.org/10.1080/10919392.2015.1125187.

[21] Hellenic Republic National Commission for Bioethics & Technoethics is a pivotal example thereof with its latest Opinions on AI in Education and Preventive Health Analytics https://bioethics.gr/en/opinions%20reports-13/opinion-on-the-artifical-intelligence-applications-in-greek-school-29.04.2025-3222 & https://bioethics.gr/en/opinions%20reports-13/the-applications-of-artificial-intelligence-in-health-in-greece-3175

interdisciplinary approaches emerge to bridge law science and justice -one of the pivotal areas of democratic ecology- with information technology to ensure a safe transition for all stakeholders concerned.

AI & Democracy: The concerns' area

Issues of the Present

Legitimacy, Delegation, Representation

People's legitimacy is the cornerstone of mandate in democratic politics. The ever-growing AI role and the questionable neutrality of "machines" could affect the citizenship-building identity and relations in liberal democracies in three areas: participation, power structures and citizen trust.[22] Some surveys indicate that many citizens around the world entertain the possibility of allowing an AI candidate to run for statehood and even an AI president to undertake the governance[23] by even electing and legitimizing an AI President,[24] meaning that we seek ways to shun corruption, nepotism and bad human judgements. By using the "disappointment" as a key argument, we may be vesting too many powers on the neutral, clean, clear-cut, fair and firstly appearing on the political scenery algorithms, thus risking the creation of new power centers, also known as "epistemic communities" that could harm cultural and civic identities via a future *commonsense* ground where machines "do it better" and that delegation is permissible at all costs.[25]

Algorithmic Decision- Making [ADM] and solutionism in modern political & statehood settings

An Algorithmic Decision-Making [ADM] system ranges from clearly statistical models and reach applications and techniques of Deep-Learning, a procedure that assigns them more agent-like character. ADM sees political decision-making as one more "cognitive task" that needs to be resolved. This embodies Solutionism the belief that technology (and in our contemporary settings AI) offers turnkey solutions for all our societal, political and bureaucratic problems.[26] Democracy however cannot be reduced to equations and statistical data; politicality, diversity and pluralism seem to resist quantification whereas solutionism risks turning citizens inpatient and willing to delegate more and faster powers to AI and ADM models.[27] Also, in terms of legitimacy, there are three limitations: (1) the lack of a ground truth needed for an optimization process; (2) the

[22] Duberry J. Artificial Intelligence and Democracy: Risks and Promises of AI-mediated citizen-government relations. Edward Elgar, Cheltenham, 2022. In: Fest IC, (book review) Utrecht School of Governance Utrecht University, 2023, p.1.

[23] Carpio A. Is it time to automate politicians? The Economist, Jul 31st, 2018.

[24] Davis D. Is There an AI President in Our Future? That Might Be an Upgrade. Wired, May 18, 2017. https://www.wired.com/2017/05/hear-lets-elect-ai-president/

[25] Antoniades A. Epistemic Communities, Epistemes and the Construction of (World) Politics. Global Society, 2003, 17(1), 21-38.

[26] Morozov E. To Save Everything, Click Here: The Folly of Technological Solutionism. PublicAffairs, New York, 2013.

[27] Jasanoff S, Kim SH. Dreamscapes of Modernity. Chicago University Press, 2015.

fragile link between outcomes to preceding political decisions; and (3) the malleability of decision contexts and public perceptions.[28] Some scholars attempt a comparison between the legitimacy of citizens and their human collective intelligence versus the estimated (or anticipated) AI ultra-intelligence or the Artificial General Intelligence; AI intelligence could erode the human voter's agency reducing citizens to passive recipients of data. Human collective intelligence offers stronger safeguards compared to the narrower ADM. The voters-government relationship and therefore delegation, representation and legitimacy are endangered by the technological determinism: if everything is pre-calculated, pre-processed and simply fed to the electorate, what will voters vote for?[29] Lastly, we should be cautious about the imaginary -a commonsense understanding of the shared vision delegation process- shaped and reproduced by rhetoric and power[30] as such imaginaries often go beyond scrutiny.[31]

Hybrid Media Systems, Echo Chambers and Filter Bubbles

The Hybrid Media System is a term that depicts how the social media platforms mutated from communication, interaction, entertainment, diffusion of cultural products channels to tangible political actors, able to shape political opinion, narratives and impact elections outcome via the control of informational flows and the construction of perception systems.[32] We are looking at politically charged algorithms that affect the future of elections, synthesis of parliaments, public administration settings by the power of the connectivity-culture that allows a channel of carefully designed information (some say computational propaganda) to the benefit or detriment of specific power centers.

Social media platforms and AI algorithms are now seen as "living and breathing political actor"[33] while deploying Machine Learning Algorithms (MLAs) to filter, rank and diffuse information,[34] thus allowing the creation of Filter Bubbles and Echo Chambers both intensifying a closed circuit of information coming the end-user's way, according to their preferences and affiliations. Filter Bubbles and Echo Chambers use the so-called *resonance effect* and the repetition technique. This cognitive

[28] König PD, Wenzelburger G. Between technochauvinism and human-centrism: Can algorithms improve decision-making in democratic politics? European Political Science, 2022, 21:6. https://doi.org/10.1057/s41304-020-00298-3.

[29] Helbing D, Frey BS, Gigerenzer G, Hafen E, Hagner M, Hofstetter Y, van den Hoven J, Zicari RV, Zwitter A. Will democracy survive big data and artificial intelligence? Scientific American 2017, 25. https://www.scientificamerican.com/article/will-democracy-survive-big-data-and-artificial-intelligence/

[30] Braun R. *op.cit.*, p.8.

[31] Harvey D. A Brief History of Neoliberalism. Oxford University Press, 2007, p.24.

[32] Chadwick A. The Hybrid Media System: Politics and Power. Oxford University Press, New York, 2017.

[33] Scholz T. Digital Labor: The Internet as Playground and Factory Routledge, New York, 2012. In: Ünver HA, *op.cit.*, 2018.

[34] Reisach U. The responsibility of social media in times of societal and political manipulation. European Journal of Operational Research, 2020, 291(3):906-917.

fragmentation could weaken political knowledge leading to political alienation and social polarization.[35]

AI Biases and Political Decision-Making

Two interactive experiments held in 2024 sounded out the effects of partisan bias in AI language models on political decision-making.[36] Participants exposed to politically biased models were significantly more likely to adopt opinions and make decisions aligned with the AI bias, regardless of their personal political partisanship. By means of content moderation, under-the-radar data harvesting and profiling techniques biases propagate disparities in content (gender etc.), discriminatory opinions, stereotypes, conspiracy theories and intolerance leaving a door open for societal polarization, racism and political violence.[37] Via "persuasive computing" citizens are nudged to specific political behaviors and judgements, thus raising concerns about the direct involvement of profit-making tech companies in the *res publica*.[38] What is more, political campaigns have undergone extreme makeover over the last decade thus affecting the voting culture and attitude all over the world.[39]

Deepfakes, Sleeper Social Bots & Political Bots

Media ecology is also bleeding out due to yet another digital apparatus, engineered by specific persons or groups of persons, yearning to disorientate the public opinion or create social uprising – the Deepfakes phenomenon. Deepfakes come with audiovisual tampered content and spread disinformation and conspiracy theories. The Malicious Use of Deepfakes (MUD) is a current social problem putting democratic institutions, international security, diplomacy and future civic societies at real risk.[40]

Sleeper Social Bots are AI agentic entities designed to remain dormant for a designated period prior to becoming active and start spreading disinformation.[41] Such bots apply psychographing and micro-targeting techniques on voters during the pre-election periods that could detrimentally affect free elections and democracy.[42]

[35] Cacciatore, MA, Yeo SK, Scheufele DA, Xenos, MA, Brossard D, Corley EA. Is Facebook Making Us Dumber? Exploring Social media Use as a Predictor of Political Knowledge. Journalism Mass Communication Quarterly, 2018, 95 (2), 404–424.

[36] Fisher J, Feng S, Aron R, Richardson T, Choi Y, Fisher DW, Pan J, Tsvetkov Y, Reinecke K. Biased AI can Influence Political Decision-Making, ArXiv, 2024. https://arxiv.org/html/2410.06415v1

[37] Rozado D. Danger in the Machine: The Perils of Political and Demographic Biases Embedded in AI Systems, Manhattan Institute, 2023.

[38] Helbing et al. *op.cit.*

[39] Tomić Z, Damnjanović T, Tomić I. AI in Political Campaigns. South Eastern European Journal of Communication, 2023, 5.

[40] Pashentsev E. Malicious Use of Deepfakes and Political Stability. Academic Conferences and Publishing International Limited, 2020.

[41] Doshi J, Novacic I, Fletcher C, Borges M, Zhong E, Marino,M C, Gan J., Mager S, Sprague D, Xia M. Sleeper Social Bots: A New Generation of AI Disinformation Bots are Already a Political Threat. University of Southern California, 2024.

[42] Brkan M. Artificial intelligence and democracy: The impact of disinformation, social bots and

Political bots share the same technological and engineering philosophy as sleeper social bots and as we will later see they have been causing some serious political turmoil in Canada and the political decision-making of the citizens, raising concerns on the identification, evidence, attribution and enforcement properties of such algorithmic apparatuses.[43]

Big Data

How can we make a rational and safe link between the Big Data and them, potentially harming democratic procedures? Once designed to enable marketing and consumption techniques Big Data are lately seen in the political scenery: fun and easy-to-use AI applications [trained with gazillions of Big Data] and social media platforms opt for profiling, targeting, shaping political campaigns featuring low transparency and questionable ethics, giving special attention to the critical "undecisive" percentage.[4445] There is quantifiable evidence that the extensive usage of Big Data in civic procedures creates an alarming drawback for democracies jeopardizing fairness, accuracy and pluralism of views while raising surveillance concerns that are inherently incompatible with democratic values.[46] Moreover, those holding the keys to Big Data centers control political voice and policymaking in various areas of governance while intensifying our concerns for accountability and transparency.

The A.R.T. Problem [Accountability, Responsibility, Transparency]

Can algorithms be truly blamed if they make a mistake, or should we put the blame on the biases uploaded by their coders and developers during the LLM training / alignment procedure? The so-called A.R.T. [Accountability Responsibility Transparency] Problem is interlinked with ADM, and the issues of legitimacy. But why is it so difficult for machines to explain themselves? Do we run the risk of stumbling on the so-called black box? Deep learning procedures deploy probabilistic setups of input nonlinear transformations to generate an acceptable level of output accuracy. If unsupervised, such probabilities end up creating inherent social uncertainties that, by design, make ADM outcomes inscrutable and opaque.

political targeting. Delphi Forum. Interdisciplinary Review of Emerging Technologies, 2019, 2 (2): 66-71. https://delphi.lexxion.eu/article/delphi/2019/2/4

[43] Dubois E, McKelvey FR. Political Bots: Disrupting Canada's Democracy. CJC Policy Portal, December 20, 2024. https://cjc.utppublishing.com/doi/pdf/10.22230/cjc.2019v44n2a3511

[44] Costa E, Halpern D. The Behavioural Science of Online Harm and Manipulation, and what to Do about it. The Behavioural Insights Team, 2019. https://www.bi.team/publications/the-behavioural-science-ofonline-harm-and-manipulation-andwhat-to-do-about-it/

[45] Woolley SC, Howard PN. Automation, Algorithms, and Politics| Political Communication, Computational Propaganda, and Autonomous Agents. International Journal of Communication, 2016, 10:4882–4890. https://ijoc.org/index.php/ijoc/article/view/6298/1809.

[46] Mavriki P, Karyda M. Big Data Analytics: Big data analytics in e-government and e-democracy applications: privacy threats, implications and mitigation. Int. J. Electronic Governance,2022, 14:4.

An explanation for any decision made should meet at least one of the following conditions[47]:

- Human-interpretable information (at least not creating new challenges) about the factors used in a decision and their relative weight
- An answer to a counterfactual question.

Lastly, algorithms are usually considered "business secrets" fact which further complicates transparency issues even though certified auditing authorities could resolve this problem, or scrutiny could apply in the blueprint algorithm.[48]

The Future: Towards the rise of new regimes?

Shoshana Zuboff has coined the term "surveillance capitalism" arguing that big tech corporates maximize end-users' content engagement via emotion-triggering content to maximize profits. In this age of surveillance capitalism, digital spaces are used as profit-seeking mechanisms instead of zones of knowledge democratization and civic emancipation.[49] Hacker wonders whether tech companies which run, engineer, deploy and monetize algorithms are willing to find ways to eliminate all the pathogenies or mitigate biases?[50] Could "state surveillance" be simply replaced by "digital surveillance" where human behavior is predictable, and forecasts turn quantifiable?

Howse introduces the term "Algorithmic Feudalism" and Treré the term "Totalitarianism Variants". Capitalizing on the Habermasian model of enclosure and distributionary monopoly, one could say that automation of information systems [including AI], lack transparency and accountability and could mitigate political representation and participation. Drawing on Engels' interpretation of totalitarianism and feudalism, power rests with whoever controls the modes of production, mirroring today's elite of IT leading companies.[51] AI Feudalism involves around the narrative of an AI corporatism system offering protection against chaotic settings. Totalitarian regimes often use technology and science in order to

[47] Doshi-Velez et al. *op.cit.* There is a significant debate going on about the Articles 13-15 of GDPR (effective May 25, 2018) and the "right to explanation" concerning the existence, logic and envisaged consequences of automated DM systems combined with the right of the Subject to refrain or decline decisions made by automated systems (Article 22 reference to: Council Regulation 2016/679, arts. 13-15, 22, 2016 O.J.(L119) 1). This debate prompts us to consider that meaningful information methods about how AI systems operate is due if we wish to receive (and therefore exercise our right to) the necessary explanation.

[48] Kavanagh D, McGarraghy S, Séamas K. Ethnography in and around an algorithm. SWG Creativity, Reflexivity and Responsibility in Organizational Ethnography, 2015. https://researchrepository.ucd.ie/handle/10197/7348

[49] Zuboff S. Big Other: Surveillance Capitalism and the Prospects of an Information Civilization. Journal of Information Technology, 2015, 30 (1):75–89. https://doi.org/10.1057/jit.2015.5

[50] Hacker P, Teaching fairness to artificial intelligence: Existing and novel strategies against algorithmic discrimination under EU law. Common Market Law Review, 2018, 55(4):1143-1185.
In: Coeckebergh M. The Political Philosophy of AI. Polity Press, 2022.

[51] Ünver HA, *op.cit.*

impose force; technology then is stripped by its "enabler" role and turns into an actor.[52] Another term to depict the same worries is "Machine Totalitarianism"; Ball and Snider argue that in totalitarian settings governors and tech companies develop a symbiotic relationship,[53] whereas Walton & Bhabani comment on the labor precarity, followed by excessive technology dominion.[54]

Responding to Marc Zuckerberg's famous phrase "AI will fix this!",[55] some scholars discern an alarming technochauvinism, namely the belief that societies (and liberal democracies) are flawed and erroneous systems that need constant "debugging" and repair, overlooking the human societal properties of diversity and polyphony.[56]

Country-specific cases

A 2019 survey launched by the Center for the Governance of Change at the Spanish IE University sees more than half of European people been ready to give machines a chance in the next-day governance of their countries.[57] In countries such as Germany and Netherlands more than 30% of the citizens would assign AI the governance. In China the 75% openly favor AI parliamentarians despite the regime's current surveillance and social scoring practices. AI / machine learning in China is embedded in the regime's militaristic narrative and could therefore have serious impact on human rights and civil liberties.[58]

60% of US respondents shun the idea of AI politicians, despite the voters' charted susceptibility to social media propaganda (Cambridge Analytica scandal).

59% of Italy's respondents favor the replacement of humans by AI while in the last elections they were found extremely engaged by TikTok political content.[59] A Dutch survey revealed a two-speed paradox: voters would welcome AI in governance, yet human politicians did not incorporate AI agenda in their

[52] Foucault M. Discipline & Punish: The Birth of the Prison, (trans. Alan Sheridan). Vintage Books, New York, 1995.

[53] Ball K, Snider L. The Surveillance-Industrial Complex: A Political Economy of Surveillance. Routledge, New York, 2013.

[54] Walton N, Bhabani S. Rethinking of Marxist perspectives on big data, artificial intelligence (AI) and capitalist economic development. Technological Forecasting and Social Change, 2021, 166(1):120576.

[55] The famous response of Facebook CEO Marc Zuckenberg when asked to give explanations in the 2018 Senate Hearing upon issues of misinformation, hate speech and privacy.

[56] Nemitz P. Constitutional democracy and technology in the age of artificial intelligence. Philosophical Transactions of the Royal Society A: Mathematical, Physical and Engineering Sciences, 2018, 376 (2133): 1–14.

[57] Results published in 2021 available at: IE University official webpage results: https://www.ie.edu/university/news-events/news/ie-university-research-reveals-1-2-europeans-want-replace-national-mps-robots/ https://www.cnbc.com/2021/05/27/europeans-want-to-replace-lawmakers-with-ai.html

[58] Cyranoski D. Beijing Launches Pioneering Brain-Science Centre. News, Nature, April 5, 2018. In: Ünver HA, *op.cit.*

[59] Battista D. For better or for worse: Politics marries pop culture (TikTok and the 2022 Italian elections). Society Register, 2023, 7(1).

latest campaigns, showing a low degree of politicization.[60]

Japan has gone one step further: in Tokyo mayoral elections, a candidate called Michihito Matsuda suggested delegating political decision-making, policy implementation and governance entirely to the machines.[61]

Six experiments held in US, Spain and Poland monitor the AI involvement in political decision-making. When it comes to political context, respondents prefer human intervention in most online encounters since humans are seen as more just than AI agents. The study also showcased an 'algorithmic aversion' of public opinion due systemic problems curatorial algorithms feature in terms of construction & deployment.[62]

A qualitative survey showed that in Indonesia's 2024 elections over 95% of Gen Z voters (aged 17-29 years) acknowledge been influenced by AI-induced campaigns via microtargeted and personalized content.[63] In Pakistan, AI curation and deepfake proliferation in the elections caused filter bubbles, misinformation and led to social and political polarization causing biases and oppression of dissidents.[64]

Canada is yet another interesting case where the political bots created the "astroturfing effect" that caused disorientation and misbalance in the last elections. Political bots initially designed as an administrative tool and a means for journalists to scrap public data, turned into instruments of computational propaganda: their ability of automated accounts creation and interaction with other account users, platforms and datasets allowed them to interfere in the online political discourse causing foggy perceptions to all internet participants.[65]

DISCUSSION

Future scenarios

Scholars' recommendations

When weighing the current bibliography, one cannot come to a safe conclusion on whether AI will harm or assist democracy, the reason why some advocate moderation: AI could be trained and remain as politically neutral as possible to make room for human intel-

[60] Morosoli S, Kieslich K, Resendez V, van Drunen M. AI Governance in the Spotlight: An Empirical Analysis of Dutch Political Parties' Strategies for the 2023 Elections, 2024.

[61] Efthymiou IP, Efthymiou -Egleton TW, Sidiropoulos S. Artificial Intelligence (AI) in Politics: Should Political AI be Controlled? International Journal of Innovative Science and Research Technology, 2020, 5.

[62] Wojcieszak et al.m *op.cit.*, p.14.

[63] Febriandy RK, Revolusi P. The Digital Political Revolution: The Impact of Artificial Intelligence (AI)-Based Political Campaigns on Voter Perceptions and Decisions in Generation Z In Indonesia. Jurnal Pendidikan Bahasa, 2024, 11(2):444-458.

[64] Raza A, Waqar AM. Algorithmic Curation in Facebook: An Investigation into the role of AI in Forming Political Polarization and Misinformation in Pakistan. Annals of Human and Social Sciences, 2024, 5, No. 2 (S): 219-232. http://doi.org/10.35484/ahss.2024(5-II-S)22.

[65] Dubois et al., *op.cit.*

ligence to keep making decisions.[66] Another moderate view suggests that since we do not know the future of technology, we should shun the attitude of treating it like a fixed event and trying to remedy for all future events.[67] Skeptics suggest that if an AI-Human symbiotic model is to be fine-tuned in a democracy-oriented manner, we need publicly open procedures for LLM models, because ADM is filtered down to all groups (socialities) affecting relational awareness. Braun suggests politicizing the ADM procedure, namely turning our look not inside the machines, but on the outside where they actually function,[68] a pathway from "polis to technopolis" echoing the work of Hannah Arendt. Civic participation, engagement and inclusion in the development process are encouraged; an "in-progress" mentality must be embraced by all stakeholders while we should also create regulatory sandboxes, responsible research and innovation, research integrity and impact-responsiveness-competence assessment instruments.[69] When it comes to political discourse, agenda setting and pre-campaign information it is argued that public interest should be at the core of ethical faculty of AI applications and tools used thereof.[70]

Monitoring our "digital well-being" and the impact of technology in our physical, mental and psychological aspects and self-understanding is also recommended[71] combined with education, particularly digital and AI literacy and critical thinking falling in the scope of "user's responsibility"; also the implementation of EU funded projects such as SHERPA, SIENNA and PANELFIT gives hope for the monitoring of human rights agenda, well-being and legislative issues rising from the extensive usage of Big Data. An increase in numbers and power of Ethics Committees and Councils is also highly recommended.[72]

Civic education is also vital in combination with digital literacy to help voters identify and avoid social / political bots and computational propaganda on an early stage. Dubois & McKelvey suggest three policy options for political bots and their astroturfing effect on elections: total ban from social media platforms; establishment of 'bot registries' where stakeholders and owners will have to insert information and comply with standardized require-

[66] Makridakis S. The Forthcoming Artificial Intelligence (AI) Revolution: Its Impact on Society and Firms. Futures 90, 2017: 46–60. https://doi.org/10.1016/j.futures.2017.03.006

[67] Müller VC. Ethics of Artificial Intelligence and Robotics. The Stanford Encyclopedia of Philosophy, 2020. (Ed. Zalta EN). https://plato.stanford.edu/archives/win2020/entries/ethics-ai/

[68] Ethics guidelines for trustworthy AI. EC. (2018c).

[69] Braun R. *op.cit.*, p.21-23.

[70] Tomić et al., *op.cit.*, p.3.

[71] Burr C, Floridi L. The Ethics of Digital Well-Being: A Multidisciplinary Perspective. In: Burr C, Floridi L (ed) Ethics of Digital Well-Being, A Multidisciplinary Approach. Philosophical Studies Series, 2020: 1–29.

[72] Christodoulou E, Iordanou K. Democracy Under Attack: Challenges of Addressing Ethical Issues of AI and Big Data for More Democratic Digital Media and Societies. Politics of Technology, a section of the journal Frontiers in Political Science, 2021:8.

ments [see DSA, AI Act already enacted in EU area]; stronger Codes of Conduct and stricter Road Maps for social platforms concerning the deployment of political bots and the disclosure obligations thereof.[73]

Some others believe that the "state action doctrine" should be applicable to AI developers and IT stakeholders holding them legally accountable just like public servants are.[74] Another interesting suggestion is to revisit the social contract in a way that fits with the latest AI / algorithmic advancements, introducing the terms of Human-in-the-Loop (HITL) and the Society-in-the-Loop (SITL). This entails drafting an algorithmic social contract (using tools to engineer, develop, program, debug and maintain the systems) where diverse human stakeholders would be mediated by AI models and machines. HITL signifies modeling, simulation and interactive ML (Machine Learning) processes whereas SITL entails the HITL accessing mechanisms to negotiate a value system and monitor the degree of compliance of AI systems with new social agreement and how various stakeholders may be affected.[75]

The issue of explanation…and a solution to the AI accountability gap

Coming back to the challenging area of explanation and accountability of AI systems, scholars propose an apparatus of Legally Operative Explanations: although many consider LLMs to be chaotic in their structure and therefore impossible to provide explanations [black box effect] we should be able to understand a distinction between transparency, namely been aware of the manners and principles a system operates and legally operative explanations, namely straightforward answering to questions posed. This is feasible if we enact two modalities: local explanation and counterfactual faithfulness.[76] On a different note, Lessig's fourth modality on system architecture as a means of regulatory constrain ("constraint of the world as I find it") means that coders' choices in design could prove more impactful in terms of transparency than strict (and often strangulating) regulation.[77]

Other scholars go by the optimization of "Sociodiversity" which is as valuable as biodiversity, fueling resilience of society and democracy to unexpected shocks leaving space for the so-called Cultural Genome Project.[78]

Questions and Techno-ethical Dilemmas

Having traced some of the latest academic voices and trends about the coupling of AI with democratic regimes and the risks for techtotalitarianism, several questions remain to be handled by governments, politicians and policymakers: Beyond a much-discussed global job losses scenario what other changes is AI likely to cause for public bureaucracies? What

[73] Dubois et al., *op.cit.*

[74] Crawford K, Schultz J. AI systems as state actors. Columbia Law Review, 2019, 119.

[75] Rahwan I. Society-in-the-loop: programming the algorithmic social contract. Springer Nature Link. Ethics Inf Technol, 2018, 20:5–14. https://doi.org/10.1007/s10676-017-9430-8.

[76] Doshi-Velez et al. *op.cit.*, p. 13-14.

[77] Bietti E. Assessing principles for the regulation of online content: Lessig's modalities of regulation. Media Laws: Law and Policy of the Media on A Comparative Perspective, 2017. https://www.medialaws.eu/wp-content/uploads/2017/01/1.2017-Bietti.pdf

[78] Helbing et al. *op.cit.*

are the challenges and bottlenecks that civil society encounters when deploying AI systems for political participation? Should we boost decentralized information systems and improve inter-operability and collaborative opportunities via digital literacy? Is the Actor-Network Theory a fit-for-all solution to our existential puzzle?

To the best of our understanding, it is advisable to map which types of AI-induced political participation are to be embraced or avoided. Furthermore, we could turn to smart regulation, digitally literate (and therefore bulletproof) constitutions, equitable resources distribution to avoid digital colonialism, while embedding ethics-by-design into AI architecture and growing long-haul strategic foresight models (including but not limited to national blueprint AI strategies). Finally, we should discern, delimit and shield the domains of national security, secrecy and diplomacy against algorithmic glitches and arrhythmia.

As homo sapiens *organic* societies and *silicon* algorithmic blueprints tend to ontologically converge, a meta-human discourse is unveiled. The scientific community is called upon to draft a roadmap for future generations and democracy: humanities must be revamped and further integrated into technological discourse. Creativity, empathy, reciprocity, diversity, pluralism, trust, solidarity and cooperation should be our guiding light.[79] From a philosophical point of view, if AI offers the gift of virtuality allowing us to contemplate alternative realities, does this give us new political and civic paradigms? New types of Governance? A Democracy of Things perhaps? Can we train our societies to avoid ethics panics, promote prudent regulation while also leaving space for innovation and research integrity and support informational self-determination?

Computational complexity and ontological myths aside, Artificial Intelligence remains a human creation that needs to be embraced and trained with humanitarian values.[80] Technoethics is a fast-growing research arena that points to the obvious: human-machines symbiosis only makes sense if we revisit the human condition and delve deeper into the meaning of life and human societies. In terms of democratic vigilance and societal awareness, perhaps it is worth spending time and resources *now* to avoid future generations been diagnosed with "civic anosoagnosia" where citizens will be unaware of their democracies been incapacitated.

[79] Tsekeris C. Industry 4.0 and the digitalisation of society: Curse or cure? Homo Virtualis, 2018, 1(1): 4–12. https://doi.org/10.12681/homvir.18622

[80] Γιαννακόπουλος Γ. Τεχνητή Νοημοσύνη: Μια Διακριτική Απομυθοποίηση. Εκδόσεις Ροπή, 2021.

Ανασκόπηση

Minors in clinical trials: balancing ethics, rights and medical innovation

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Abstract

This report explores the complex intersection of medical innovation, ethics and the rights of minors participating in clinical trials. While pediatric clinical research is fundamental for developing effective treatments, it also raises significant ethical concerns due to the vulnerability of this population, which stems from their reliance on parents and caregivers and their limited ability to fully comprehend the procedures involved.

The report addresses key issues such as the principle of informed consent and the requirement of assent, drawing from the legal framework governing this area. This includes instruments such as the UN Convention on the Rights of the Child and the EU Clinical Trials Regulation.

The guiding principle in all pediatric decisions is the child's best interest, which ultimately shapes ethical and legal parameters of clinical research. Risk/benefit assessments are crucial and must inform all stages of the clinical trial. Other essential safeguards include the right to withdraw from a trial and the right to be informed or not to be informed about one's medical condition. The report also examines situations of parental disagreement.

The ethical role of ethics committees is highlighted, particularly their responsibility to ensure the legitimacy of consent and prevent undue influence. The report stresses the need for these committees to include experts in pediatric ethics and child development.

Practical challenges are also explored, such as the difficulty of assessing risk, particularly with infants and children who cannot articulate discomfort. Innovative multimedia methods for explaining trials to children and parents are examined as ways to improve understanding and transparency. Special attention is given to modern controversial practices, including the use of healthy children as stem cell donors for their siblings and the use of hypothermia in cases of perinatal hypoxic ischemic encephalopathy.

The report concludes by arguing that excluding minors from clinical trials in the name of protection would unjustly deprive them of access to potentially life-improving treatments. Instead, clinical trials must be conducted not on children but with children, ensuring that respect of their rights, needs and demands is at the heart of every decision.

Keywords: Clinical trials, minors, informed consent, child's best interest, medical ethics.

Ανήλικοι σε κλινικές δοκιμές: εξισορρόπηση της ηθικής, των δικαιωμάτων και της ιατρικής καινοτομίας

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Περίληψη

Το άρθρο αυτό εξετάζει τη σύνθετη αλληλεπίδραση μεταξύ της ιατρικής καινοτομίας, της δεοντολογίας και των δικαιωμάτων των ανηλίκων που συμμετέχουν σε κλινικές δοκιμές. Αν και η παιδιατρική κλινική έρευνα είναι θεμελιώδης για την ανάπτυξη αποτελεσματικών θεραπειών, εγείρει επίσης σημαντικά δεοντολογικά ζητήματα λόγω της ευαλωτότητας αυτού του πληθυσμού, η οποία οφείλεται στην εξάρτηση των ανηλίκων από τους γονείς και φροντιστές τους και στην περιορισμένη ικανότητά τους να διαμορφώσουν και να εκφράσουν βούληση.

Το άρθρο εξετάζει βασικά ζητήματα, όπως η αρχή της ενήμερης συναίνεσης, με βάση το νομικό πλαίσιο που διέπει τον τομέα αυτόν, όπως η Σύμβαση των Ηνωμένων Εθνών για τα Δικαιώματα του Παιδιού και ο Κανονισμός της ΕΕ για τις Κλινικές Δοκιμές.

Η κατευθυντήρια αρχή σε όλες τις παιδιατρικές αποφάσεις είναι το συμφέρον του παιδιού, το οποίο τελικά διέπει τους ηθικούς και νομικούς όρους της κλινικής έρευνας. Οι αξιολογήσεις κινδύνου/οφέλους είναι ζωτικής σημασίας και πρέπει να αφορούν όλα τα στάδια της κλινικής δοκιμής. Άλλες βασικές εγγυήσεις περιλαμβάνουν το δικαίωμα απόσυρσης από μια δοκιμή και το δικαίωμα ενημέρωσης ή μη ενημέρωσης σχετικά με την ιατρική κατάσταση του ατόμου. Η μελέτη εξετάζει επίσης περιπτώσεις διαφωνίας των γονέων.

Τονίζεται ο ηθικός ρόλος των επιτροπών δεοντολογίας, ιδίως η ευθύνη τους να διασφαλίζουν τη νομιμότητα της συγκατάθεσης και να αποτρέπουν την άσκηση αθέμιτης επιρροής. Υπογραμμίζεται εξ άλλου η ανάγκη να περιλαμβάνουν αυτές οι επιτροπές εμπειρογνώμονες στον τομέα της παιδιατρικής δεοντολογίας και της ανάπτυξης του παιδιού.

Εξετάζονται επί πλέον ορισμένες πρακτικές προκλήσεις, όπως η δυσκολία εκτίμησης του κινδύνου, ιδίως σε βρέφη και παιδιά που δεν μπορούν να εκφράσουν την δυσφορία τους. Παρουσιάζονται καινοτόμες μέθοδοι πολυμέσων για την εξήγηση των δοκιμών σε παιδιά και γονείς ως τρόποι βελτίωσης της κατανόησης και της διαφάνειας. Ιδιαίτερη προσοχή δίνεται σε σύγχρονες αμφιλεγόμενες πρακτικές, όπως η χρήση υγιών παιδιών ως δοτών βλαστικών κυττάρων για τα αδέλφια τους και η χρήση υποθερμίας σε περιπτώσεις περιγεννητικής υποξικής ισχαιμικής εγκεφαλοπάθειας.

Το άρθρο καταλήγει υποστηρίζοντας ότι ο αποκλεισμός των ανηλίκων από τις κλινικές δοκιμές με το πρόσχημα της προστασίας τους θα τους στερούσε άδικα την πρόσβαση σε θεραπείες που ενδέχεται να βελτιώσουν τη ζωή τους. Αντίθετα, οι κλινικές δοκιμές πρέπει να διεξάγονται όχι «σε» παιδιά αλλά «με» παιδιά, διασφαλίζοντας ότι ο σεβασμός των δικαιωμάτων, των αναγκών και των απαιτήσεών τους βρίσκεται στο επίκεντρο κάθε απόφασης.

Λέξεις κλειδιά: Κλινικές δοκιμές, ανήλικοι, ενήμερη συναίνεση, συμφέρον του παιδιού, ιατρική ηθική**.**

The World Health Organization (WHO) defines clinical trials as "*a type of research that studies new tests and treatments and evaluates their effects on human health outcomes*".[1] Everybody can take part in clinical trials, including minors.

Article 1 of the UN Convention on the Rights of a Child defines a minor as a person under 18.[2] However, the legal definition of a minor varies across States. As stated in Article 2, paragraph 2.18 of the EU Clinical Trials Regulation, a minor is "*a subject who is, according to the law of the Member State concerned, under the age of legal competence to give informed consent*".[3] Therefore, the notion is subject to national law.

Historically, children were excluded from trials, as they were considered a vulnerable population incapable of expressing their will. This opinion started to change during the AIDS epidemic of the 1980s, as "*the choice for children was either to include them in risky research or to allow them to die from AIDS*".[4]

Paragraph 3 of EU Regulation (EC) No 1901/2006 highlights the risks associated with the past dismissal and oversight of pediatric clinical trials, including issues such as adverse reactions, underdosing, and the lack of tailored formulations for pediatric medicines.[5]

Children's distinct and exclusive characteristics make them a different population, differentiating them from adults. Due to these substantial differences, clinical trials may provide different results depending on whether participants are minors or adults. Thus, including children in clinical trials can lead to important outcomes in addressing pediatric illnesses, which might not be achievable otherwise. Children often require specific medications instead of adjusted doses or modified versions of adult therapies.

Pediatric clinical trials are essential not only for developing cures for sick patients but also for preventing illnesses and improving overall child health.

However, involving minors in clinical trials raises important moral concerns. While pediatric clinical research is undeniably important for medical advancement, it is fundamental to balance these needs with the rights and demands of both patients and their parents.

1.1 The protection of children's rights

As a vulnerable population that may face difficulties in expressing their will, children are a central interest in numerous legislative frameworks.

The Convention on the Rights of the Child, signed by 196 countries, is one of the most

[1] World Health Organization: Definition of clinical trials, Accessed 5.11.2024.

[2] UN Convention on the Rights of the Child, 20 November 1989, General Assembly resolution 44/25, Article 1.

[3] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, Article 2.

[4] *Idem*, p. 364.

[5] Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use, Paragraph 3.

significant international agreements concerning the protection of minors' rights. Its 54 articles address various areas of childhood and recognize an extensive set of rights, including in the medical field.

Article 24 recognizes children the right to health and health services, establishing a duty for States Parties to ensure every child's right to the highest attainable standard of health, providing access to facilities for the treatment of illnesses and the rehabilitation of health. Clinical trials play a significant role in advancing medical knowledge, thereby contributing to the objective of pursuing "*full implementation of this right*".[6]

Another important principle is outlined in Article 3, as it states that the guiding criterion should always be the child's best interest.

The child's best interest is also the leading criterion used in the Charter of Fundamental Rights of the European Europe, Article 24, paragraph 2: "*In all actions relating to children, whether taken by public authorities or private institutions, the child's best interest must be a primary consideration*".[7]

2. The main sources of regulation

Clinical trials' main sources of regulation are the following:

- The EU Clinical Trials Regulation No. 536/2014
- The 69th World Health Assembly Resolution on promoting innovation and access to quality, safe, efficacious and affordable medicines for children[8]
- The Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, also known as the 'Oviedo Convention'[9]
- The Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research[10]
- The World Medical Association (WMA)'s Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Participants, adopted by the 18th WMA General Assembly, Helsinki, Finland in 1964 and lastly amended by the 75th WMA General Assembly, Helsinki, Finland in October 2024[11]

The EU Regulation No. 536/2014 aims to provide a harmonized statute regarding the medical field of clinical trials and to achieve a balance between two priorities: the protection of minors and the advancement of research, in order to discover new or improved treatments.

The EU relies on a system centered on the use of a single portal, called Clinical Trials

[6] UN Convention on the Rights of the Child, Article 24, paragraph 2.

[7] The Charter on Fundamental Rights of the European Union (2012/C 326/02).

[8] 69th World Health Assembly Resolution, 27 May 2016.

[9] The Oviedo Convention, 4 April 1997, European Treaty Series No. 164, Council of Europe.

[10] The Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research, 25 January 2005, Council of Europe Treaty Series No. 195, Council of Europe.

[11] World Medical Association: Declaration of Helsinki, Accessed 10.11.2024.

Information System (CTIS), which became the only EU portal available starting from 31 January 2023.

The 69th World Health Assembly Resolution emphasizes the necessity "*to strengthen research and development on appropriate medicines for diseases that affect children, to ensure that high-quality clinical trials for these medicines are conducted in an ethical manner and to collaborate in order to facilitate innovative research and development on, formulation of, and timely regulatory approval of, provision of adequate and prompt information on, and rational use of, medicines for children, including generic medicines*" (Paragraph 8).

Paragraph 9 highlights the urgency "*to facilitate clinical trials of medicines for children based on sound ethics, needs and principles of patient protection, and to promote clinical trial registration in any registry1 that provides data to the WHO International Clinical Trials Registry Platform and to make information on those trials publically available, including publication of summary and complete data of completed trials in accordance with national and regional legislative frameworks, as appropriate*".

The general goal is to support scientific advancement; consequently, the legal framework must adapt accordingly in all fields, including clinical trials, to improve children's health. As recommended by the Resolution, this development must "*incorporate consideration of the needs of children based on the national situation*".

The Resolution also underscores the importance of transparency throughout the process.

The Oviedo Convention is the only international legally binding instrument on the protection of human rights in the biomedical field. Its primary aim is to "*protect the dignity and identity of all human beings*", [12] particularly in the areas of biology and medicine.

The Convention sets out a series of principles and prohibitions, the most important being the principle of informed consent.

The Additional Protocol to the Convention on Human Rights and Biomedicine establishes a leading principle: the primacy of human beings. Article 3 states that "*The interests and welfare of the human being participating in research shall prevail over the sole interest of society or science*".

The Declaration of Helsinki lies on the key assumption that patients' health and well-being must always be the doctors' primary consideration (Article 3). This principle extends also to the research field: according to Article 4, "*It is the duty of the physician to promote and safeguard the health, well-being and rights of patients, including those who are involved in medical research*".

Furthermore, the Declaration also sets the principle of compensation for participants: if the participants are harmed in the clinical trial process, they have the right to receive appropriate compensation (Article 15).

[12] Council of Europe, Human Rights and Biomedicine: Oviedo Convention and its Protocols, Accessed 10.11.2024.

Important guidelines are also provided by the World Health Organization (WHO) and the European Medicines Agency (EMA),[13] along with national institutions such as the National Health System UK (NHS).

In particular, the WHO deploys a particular software, called ICTRP (International Clinical Trials Registry Platform),[14] which serves as a portal that classifies pediatric clinical trials using a combination of filters and a unique algorithm. The first filter is age (0 – 18 years), whilst the second filter uses over 4000 key terms, such as "abandoned child", "acquired immunodeficiency syndrome" and "ADHD". The age filter is designed to be the most effective one: only when this filter fails does the second filter come into play.

3. Requirements for the conduction of clinical trials

According to Article 16 of the Oviedo Convention, one of the conditions under which research may be conducted is that "*the risks which may be incurred by that person are not disproportionate to the potential benefits of the research*". This establishes a risk/benefit proportionality criterion.

When a minor is involved, Article 17 of the Oviedo Convention permits research only if it has the potential to produce "*real and direct benefit to his or her health*", it cannot be conducted on another "population" (e.g. adults), it has been authorized in writing by the patient's legal representatives and the minor does not object.

If the research does not meet the condition of direct benefit, it may still be exceptionally authorized if the study can contribute to "*the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same age category or afflicted with the same disease or disorder or having the same condition*" and if it involves "*only minimal risk and minimal burden for the individual concerned*".

Thus, for research involving minors, the Oviedo Convention emphasizes that it must be aimed primarily at the patient's well-being. Exceptions are made only for studies that are critical for providing considerable findings for science, provided they impose no more than minimal risk and burden. For example, drawing a blood sample is a classic case of a minimal-risk procedure.

Regarding whether it is always necessary to separate children and adult participants in clinical trials, Article 17 of the Oviedo Convention states that pediatric clinical trials can be undertaken if they are the sole means of obtaining crucial information about certain diseases that cannot otherwise be achieved. In these situations, it is required to separate children and adults to account for the specific ways that diseases affect each group.

Article 17 of the Additional Protocol defines the criteria for "*minimal risk and minimal burden*".

Minimal risk entails that, given the nature and the scale of the intervention, the effects of the study are, if anything, forecasted to cause only a "*slight and temporary negative impact*

[13] European Medicines Agency, Accessed 10.11.2024.

[14] World Health Organization: International Clinical Trials Registry Platform (ICTRP), Accessed 10.11.2024.

on the health of the person concerned". Minimal burden refers to the study producing only a "*temporary and very slight*" discomfort for the patient.

According to the Explanatory Report, "*the notions of risk and burden include not only physical risks and burdens but also social or psychological risks to the participant*".[15]

The term *benefit* encompasses a variety of considerations. First, the beneficial scope of the research may not only involve curing the disease, but also lessening the pain caused by the disease itself and providing relief to the patient. Additionally, benefits may not be limited to the direct advantages for the research participant. In some cases, there may be no cure for the disease, or the participants may not be ill in the first place. Instead, the benefit may extend to the scientific community or other patients. This means that a minor could participate in a clinical trial aimed at finding a cure for their disease, even if the minor themselves would not directly benefit from their participation.

However, an important question arises: where do the limits of benefit lie? Can benefit be justified in light of the principle of human dignity, set forth by the Oviedo Convention itself? Does this approach risk using the patient as an instrument for general research purposes?

Although Article 16 of the Helsinki Declaration states that "*Medical research involving human participants may only be conducted if the importance of the objective outweighs the risks and burdens to the research participants*" (Article 16), if the term benefit is interpreted too broadly, there is a risk of undermining the protections guaranteed by Article 3 of the Oviedo Convention. In fact, Article 3, in stressing the primacy of individuals over the interest of society or science, is an important safeguard against the exploitation of patients in clinical trials. The Article recalls that the rights, dignity, and well-being of individual participants must remain the ultimate guiding criteria of medical research ethics.

Thus, researchers must not prioritize medical advancement at the expense of participants' physical or emotional well-being, regardless of the width of the potential benefit involved.

To further safeguard against this, minors have the right to raise concerns. If they object, the research must be interrupted in accordance with the principles of autonomy and dignity ("*The wish of the person concerned prevails and is always decisive*").[16] Moreover, the study must meet scientific, ethical and legal standards and be authorized by the qualified institution.

Throughout the process, the patient's dignity must always be respected and it must serve as a guide when deciding how to carry out the research.

[15] Explanatory Report to the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research, p. 5.

[16] Explanatory Report to the Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, p. 16.

The Additional Protocol specifies and reinforces the general rules outlined in the Convention, as research may only be undertaken if:

- "*there is no alternative of comparable effectiveness*" (Article 5)
- it does not "*involve risks and burdens to the human being disproportionate to its potential benefits*" (Article 6)
- it "*has been approved by the competent body after independent examination of its scientific merit, including assessment of the importance of the aims of research, and multidisciplinary review of its ethical acceptability*" (Article 7)

Furthermore, Article 9 of Additional Protocol states that every research project must be ethically justified and approved by an independent ethics committee. The committee's primary aim is to protect "*the dignity, rights, safety and well-being of research participants*".[17] In particular, it must assess whether participation in the research is motivated by financial interests or any other undue influence (Article 12).

Every State employs a different system, so the notion of an 'ethics committee' is broad, encompassing any body "*authorised to review biomedical research involving interventions on human beings*"[18]. For example, Brazil relies on a system that revolves around the supervision of the National Research Ethics Board – Comissao Nacional de Etica em Pesquisa (CONEP).[19] Moreover, there is a strong support around physicians and researchers for the creation of a Latin American pediatric research network to better manage multicenter clinical trials.[20]

An interesting case is Germany, where, following the implementation of the EU Clinical Trials Regulation and the German Medicinal Products Act,[21] the authorization of any clinical trial is issued by the competent national competent authority, taking into account the ethics committee's favourable opinion on the matter.[22] Thus, in the German context, there is a strict cooperation between these two bodies.

3.1 Informed consent

Informed consent is universally acknowledged as a necessary requirement for medical procedures, including clinical trials. Consent needs to be present from the beginning throughout the whole process.

Since children are minors, parents are legally required to provide consent for their participation in clinical trials. However, this alone is not sufficient: the child must also be given a clear explanation of the procedure they

[17] The Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research, Article 9 paragraph 2.

[18] Explanatory Report to the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research, p. 8.

[19] Arenas-López S, Fajardo C, Valls i Soler A, García-Corzo JR, Lima-Rogel MV, Calle G, Leite R, Lobos E, Hume-Wright Q, MacLeod S., Pediatric clinical trials in Latin America and Guyana: present views of local practitioners and ways to embrace the future, Paediatr Drugs. 2011 Aug 1;13(4):257-65, p. 259.

[20] *Ibidem.*

[21] Medicinal Products Act, Arzneimittelgesetz – AMG, Section 40.

will undergo and provide their assent to it. Thus, even though minors are not legally able to consent, they must not be excluded from the process.

The Oviedo Convention provides one of the most comprehensive frameworks on the matter.

Article 5 establishes that "*An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time*". The term '*intervention'* encompasses a wide range of medical procedures, including research.

Article 2, paragraph 2.21 of the EU Clinical Trials Regulation defines informed consent as "*a subject's free and voluntary expression of his or her willingness to participate in a particular clinical trial, after having been informed of all aspects of the clinical trials that are relevant to the subject's decision to participate or, in case of minors and of incapacitated subject, an authorisation or agreement from their legally designated representative to include them in the clinical trial*".

The general framework for consent is subject to derogations when it involves individuals unable to give consent, including minors. In these cases, Article 6 of the Oviedo Convention specifies that "*Subject to Articles 17 and 20 below, an intervention may only be carried out on a person who does not have the capacity to consent, for his or her direct benefit. Where, according to law, a minor does not have the capacity to consent to an intervention, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law. The opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity*". Thus, while parents' or caregivers' consent is essential, the patient's opinion must also be considered.

Regarding this matter, the '*Informed Consent and Assent Tool Kit*' provided by the European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA)[23] employs a list of countries, categorizing them based on whether consent is required from one or both parents. For instance, Hungary, Ireland and Spain require the consent of only one parent, whereas Italy, Germany, France and Portugal require the consent of both.

It is useful to define the elements that form the basis of informed consent.

The minor's legal representatives "*shall be given adequate information in a comprehensible form*", which covers "*the purpose, the overall plan and the possible risks and benefits of the research project, and include the opinion of the ethics committee*".[24]

The same information must also be provided to the minor, "*unless this person is not in a state to receive the information*" (for instance, if they are in a comatose state).[25]

It is interesting to note that the criteria for determining whether a person is unable to consent vary across Europe: some countries require an empirical verification in each specific case, whereas others apply a system of legal incapacitation, "*whereby a person may be declared incapable of consenting to one or*

[23] Lepola P, Needham A, Mendum J, *et al*, Informed consent for paediatric clinical trials in Europe, Archives of Disease in Childhood 2016;101:1017-1025.

[24] Additional Protocol to the Oviedo Convention, Article 16 paragraph 1.

[25] Additional Protocol to the Oviedo Convention, Article 15 paragraph 1.

several types of act"[26]. Each State determines its approach according to its own legislation.

3.2 Withdrawal of consent

According to Article 6 of the Oviedo Convention, the person representing the minor can withdraw their authorization at any time, provided it is done "*in the best interests of the person concerned*". The best interest of the patient should always serve as the guiding criteria in decision-making.

This principle has important implications when it comes to the withdrawal of consent. While a person who is able to consent may decide to withdraw it at any time – even against medical advice and despite potential negative consequences –, the same rule does not apply with minors: here, withdrawal of consent is permissible only if it aligns with the patient's best interest.

3.3. Consent in emergency situations

The Oviedo Convention clarifies the legal framework in emergency situations in Article 8: "*When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned*". In emergencies, doctors do not need to wait for the patient's parents' authorization. However, this applies only to situations that cannot be postponed.

3.4 Assent

Consent differs from assent.

While the Oviedo Convention does not define assent, the EU Clinical Trial Regulation provides clarity. According to Article 29, paragraph 8, "*in addition to the informed consent given by the legally designated representative, a minor who is capable of forming an opinion and assessing the information given to him or her, shall also assent in order to participate in a clinical trial*".

At a national level, countries like Germany require that if a minor has the 'capacity to understand', their assent must be obtained to participate in the research.[27]

An interesting example is the concept of 'Gillick competence', a common law standard used to assess whether a minor is able to provide consent to a medical procedure. Minors are 'Gillick competent' if they reach "*an age and maturity to judge what the treatment entails and assess its benefits and disadvantages*".[28]

Subcategories that divide minors in different age groups are very common. For example, the document "*Ethical considerations for clinical trials on medicinal products conducted with minors*",[29] provides specific guidance regarding assent: newborns and infants are entirely unable to provide

[26] Explanatory Report to the Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, p. 7.

[27] Buchner B, Hart D. Research with minors in Germany, Eur J Health Law. 2008 Jul;15(2):127-34, p. 130.

[28] Cave E. Seen but not heard? Children in clinical trials. Med Law Rev. 2010 Winter;18(1):1-27, p. 5.

[29] Ethical Considerations for clinical trials on medicinal products conducted with minors, 2017, p. 13.

assent; pre-schoolers (2-5 years of age), although often not able to express an opinion, should still be given information appropriate to their age and maturity; school-aged children (6-9 years of age) are generally capable of providing assent and should therefore be informed and asked for it; finally, adolescents should always be informed and asked to provide their agreement.

However, when deciding whether a minor can provide assent, it is important not to focus only on their age. Researchers should also consider "*factors such as developmental stage, intellectual capacities (e.g. children with special needs and/or learning difficulties), and life/disease experience*".[30]

Although assent may be perceived as a 'light' requirement compared to consent, this should not be the case. As the Nuffield Council on Bioethics states, "*where children and young people have sufficient maturity and understanding to make their own decision but are not yet treated as fully 'adult' by the law of their country*",[31] their assent should still be obtained. When this is not possible because they do not have the necessary capacity or maturity, they should nonetheless be involved in the decision-making process. As the Council emphasizes, "*it is the process of involvement that is ethically significant*".[32]

Therefore, assent is a distinct and necessary requirement alongside informed consent. It stresses the fact that children are not instruments or test subjects, but rather active participants who must engage with the procedure. Assent has legal value and depends on the child's level of maturity.

3.5 When the child does not agree

Both the EU Clinical Trials Regulation and the Oviedo Convention emphasize that the minor's wishes must be considered, in line with the principle of respect for human dignity.

Article 32, paragraph 1.c of the EU Regulation states that "*the explicit wish of a minor who is capable of forming an opinion and assessing the information referred to in Article 29(2) to refuse participation in, or to withdraw from, the clinical trial at any time, is respected by the investigator*". This provision refers to the concept of dissent.

Dissent does not always need to be explicit: if a State Member requires the child's assent as a condition for participation, the absence of assent corresponds to dissent.

In a hypothetical scenario where a child disagrees with their parents about participating in a clinical trial, researchers are ethically and legally obliged to immediately cease the trial in accordance with the child's will.

3.6 Right to be informed and not to be informed

According to Article 10, paragraph 2 of the Oviedo Convention, "*Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed*". Certain restrictions may apply in exceptional cases.

The Convention states that all patients have a right to be informed about their health; however, a different situation may arise when the patient is a minor. Children may not be able to comprehend the meaning of the words, especially if they are in the preschool-age area.

Data shows that in some cases it is difficult not only for minors but also for parents to accurately understand the information provided about the project. To address this issue, some scholars have introduced a new method worth examining. Approved by the

[30] *Idem*, p. 12.
[31] Nuffield Council on Bioethics (UK), Children and clinical research: ethical issues, March 2015, p. 148.
[32] *Idem*, p. 175.

University of Michigan's Institutional Review Board,[33] it focuses on using multimedia programs instead of traditional paper documents. In the study, both parents and minors were randomly assigned information either on paper or through an iPad program. The programs used 2 and 3-D images along with a voice-over that narrated the text displayed on the screen. The study demonstrated that minors who received information through the multimedia service had a significantly better understanding of the clinical trial compared to their peers who used traditional paper documents.

Interactive media is especially useful for conveying information to both parents and minors in the most effective and accessible way. Both visual and auditory elements are engaging for children and should therefore be implemented more widely.

The Convention also recognizes the patient's right 'not to know': sometimes it may be justifiable that children are kept hidden from this kind of information to protect their feelings. However, this right is controversial because it is not directly exercised by the minor. Instead, it is the parents or legal representative who decide to apply this form of protection, often without the child's say. It is a form of guardianship imposed without considering whether minors actually want to be kept hidden from receiving information about their health. Overall, the right not to know frictions with the principle of human dignity and respect for the person.

4. The role of parents and caregivers

After acknowledging the legal obligation for parents or caregivers to provide informed consent, it is important to emphasize the implications of their role.

According to the Nuffield Council of Bioethics,[34] when deciding whether to agree to their child's participation in a clinical trial, parents should evaluate three key ethical considerations.

First, they should have respect for their child as an individual; this means treating their child as a participant and not just a means to discover new scientific knowledge, considering their personal preferences and opinions, regardless of their age and maturity. Children should not be forced to do something they do not want to.

Second, they should recognize their child's developing capacity of making decisions, meaning helping them throughout their life to understand themselves and the proper way to make conscious decisions. Through their parents' help, children should be able to have the means to understand the risks of the procedure and refuse to participate.

Finally, they should always bear in mind their child's welfare. The concept of best interest, as outlined in many pieces of legislation seen before, is not always helpful due to its vagueness: sometimes it is not clear if it is in the best interest of the child

[33] Tait AR, Voepel-Lewis T, Levine R., Using digital multimedia to improve parents' and children's understanding of clinical trials, Arch Dis Child. 2015 Jun;100(6):589-93.

[34]Nuffield Council on Bioethics (UK), Children and clinical research: ethical issues, March 2015, p. 102.

participating or not in the clinical trials, since they are innovative procedures which do not often guarantee results. Parents should be concerned about the possible pain and discomfort their child may feel during the whole process, as well as long-term effects, while also considering the possible benefits.

4.1 Disagreement between parents

Although there is no specific legal provision addressing the hypothesis of parental disagreements in the context of clinical trials, the UK Research and Innovation (UKRI) provides a useful guideline. According to UKRI, while consent from just one parent or caregiver is sufficient for the clinical trial to be authorized, "*it is good practice to involve both parents and, if there is disagreement, then it is advisable to exclude the child from the research (unless it provides access to treatment that is otherwise unavailable)*".[35]

The UK National Health System (NHS) provides additional clarity. It states that "*By law, healthcare professionals only need one person with parental responsibility to give consent for them to provide treatment*", but "*In cases where one parent disagrees with the treatment, doctors are often unwilling to go against their wishes and will try to gain agreement. If agreement about a particular treatment or what's in the child's best interests cannot be reached, the courts can make a decision*".[36]

In conclusion, when one parent or legal representative does not agree to their child participating in the clinical trial, researchers should attempt a negotiation by discussing with the dissenting party. However, if the trial presents significant potential benefits for the child, an intervention of the court may be necessary.

5. Ethical questions about participation in clinical trials

Since clinical trials are highly innovative and rely on voluntary participation, often without any guarantee of results and, in some cases, even with the risk of potential harm, they raise significant moral and ethical concerns, especially when minors are involved.

Regarding this matter, the EU document "*Ethical considerations for clinical trials on medicinal products conducted with minors*" (2017) outlines four key principles that should guide the conduct of clinical trials: beneficence, non-maleficence, respect for persons and justice.[37] The first one refers to "*the ethical obligation to secure/promote well-being*", whereas non-maleficence entails the "*obligation to avoid harm*". Respect for persons means the obligation to "*treat individuals as autonomous agents and protect those with diminished autonomy*", such as children. Finally, justice is the "*fair distribution of risk, burden and benefits of research*".

Another key principle is proportionality: risks associated with clinical trials are ethically justifiable only if there is a 'proportionate

[35] UKRI: Involving Children in Research, p. 7.
[36] National Health System, Accessed 10.11.2024.
[37] Ethical Considerations for clinical trials on medicinal products conducted with minors, 2017, p. 5.

counterpart', mainly a direct benefit for the participant.[38]

In the current debate, there are two types of clinical trials that are particularly controversial.[39]

The first one concerns the use of healthy children as stem cells donors for their siblings. Bone marrow donations are a common practice, but they still carry potential risks for the donor, making it difficult to categorize them as 'minimal risk' procedures.

The second controversy concerns the use of hypothermia to treat infant perinatal hypoxic ischemic encephalopathy. This is a controversial procedure debated among scholars: some view it as very promising, while others remain skeptical. The use of hypothermia particularly highlights the challenging balance that researchers and ethics committees face when deciding if there is sufficient evidence to confidently assert that an innovative treatment is both better than the standard one and safe for minors.

Both procedures require a thorough evaluation of risks and benefits, as well as a highly specific process of informed consent.

The central problem is balancing two competing needs: on one hand protecting children from the risks associated with clinical trials and, on the other hand, ensuring they have access to potentially life-changing scientific research.

However, measuring risks in clinical trials is not easy. First, there is no precise mathematical formula capable of fully assessing them. Secondly, a universal definition of risk or discomfort does not exist because minors respond differently to medical procedures as they may have different pain tolerances. For instance, clinical trials involving newborns are particularly challenging to assess from an ethical perspective: as a matter of fact, newborns tend to cry during any kind of medical procedure, as crying at that age is often a response to unknown stimuli. Therefore, should crying be interpreted as a form of dissent or are researchers ethically justified to proceed?

The difficulty of assessing risks is further complicated by the common mistake made by researchers to treat participants the same: in particular, if we consider participants as a homogeneous group, we risk not considering individual health backgrounds. Therefore, researchers must consider "*the heterogeneity of the pediatric population and the large diversity of research projects*".[40]

Moreover, the debate also revolves around the concept of assent, in particular what it entails and when a child is capable of providing it. How can we ensure that children fully understand the procedures involved and how can we guarantee that their voices are heard and their opinions respected? Not all minors are capable of expressing their opinion: babies cannot speak and some children may be permanently or temporarily unable to do so

[38] Bos W, Tromp K, Tibboel D, Pinxten W. Ethical aspects of clinical research with minors, Eur J Pediatr. 2013 Jul;172(7):859-66, p. 863.

[39] Laventhal N, Tarini BA, Lantos J. Ethical issues in neonatal and pediatric clinical trials. Pediatr Clin North Am. 2012 Oct;59(5):1205-20.

[40]Bos W, Tromp K, Tibboel D, Pinxten W. Ethical aspects of clinical research with minors, Eur J Pediatr. 2013 Jul;172(7):859-66, p. 865.

due to disabilities or conditions, such as being in a coma.

Additionally, to express an informed opinion, it is essential that the child's maturity is properly evaluated to determine whether they are capable of forming a mature will. However, a potential conflict of interests may arise, as maturity is assessed by the clinical trial investigators themselves, who often have a personal interest in recruiting volunteers. Considering this, it might be more appropriate for an independent agent or specialized body, such as the ethics committee, to be responsible for assessing the maturity of participants. For instance, the EU Regulation No 1901/2006[41] suggested the establishment of an ad hoc scientific body within the European Medicines Agency known as the Paediatric Committee (PDCO), whose main role is "*to assess the content of paediatric investigation plans (PIPs)*".[42]

For all these reasons, there need to be higher protection thresholds to allow pediatric clinical trials.

Furthermore, it is crucial that ethics committees are formed by members with appropriate pediatric expertise. This does not simply mean "*having professionally worked with children'*, but also entails possessing the proper '*education, training and experience on various aspects of ethics, child development and psychosocial aspects*".[43] All members must have comprehensive knowledge of childhood, even if in practice it is extremely challenging to find individuals who meet all the required criteria.

Additionally, pediatric clinical trials require a continuous follow-up process, which is commonly longer than adult research in order to monitor the long-term effects.

To minimize pain and distress during clinical trials, strict guidelines must be followed: "*physical pain and distress intensity must be assessed and regularly monitored, and treated according to guidelines, particularly in neonates and children who cannot express it verbally*".[44] Doctors should prioritize less painful and invasive procedures, and analgesia or sedation should be used when necessary.

Emotional distress should also be addressed by ensuring that children are constantly reassured in a nurturing environment and, if possible, not separated from their families.

In my opinion, it would be unfair to exclude children from access to clinical trials in the name of a so-called protection purpose. Exclusion would mean denying them the possibility to improve their quality of life.

It is also true that, although it cannot be denied that clinical trials are a fundamental milestone in the scientific scene due to their potential value in research, this function needs to be balanced with the protection of minors,

[41] EU Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use, Paragraph 8.

[42] EMA: Paediatric Committee (PDCO), Accessed 22.11.2024.

[43] Ethical considerations for clinical trials on medicinal products conducted with minors, 2017, p. 14.

[44] Ethical considerations for clinical trials on medicinal products conducted with minors, 2017, p. 16.

who are a vulnerable population that in most cases face difficulties in expressing their will.

On one hand, the Declaration of Helsinki states that "*The primary purpose of medical research involving human participants is to generate knowledge to understand the causes, development and effects of disease, improve preventive, diagnostic and therapeutic interventions and ultimately to advance individual and public health*" (Article 7), but it is also inarguable that the leading criteria should always be the right to life, health, dignity, integrity and the respect for person. In fact, as the Declaration itself states, "*These purposes can never take precedence over the rights and interest of individual research participants*" (Article 7).

In conclusion, the real challenge in the clinical trials area is to assess the risk/benefit threshold, parental informed consent and child assent. Clinical research must "*be with children and young people, not on them*";[45] this means that clinical trials should not use children as a mere means to the superior end of reaching scientific advancement, but respect their person and their opinions, remembering that, although vulnerable, they are still human beings who deserve to be recognized and heard.

[45] Nuffield Council on Bioethics (UK), Children and clinical research: ethical issues, March 2015, p. 172.

Bibliography

Legislation:

- UN Convention on the Rights of the Child, 1989, General Assembly Resolution 44/25.
- EU Regulation No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use.
- EU Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use.
- The Charter on Fundamental Rights of the European Union (2012/C 326/02).
- 69th World Health Assembly Resolution, 27 May 2016.
- The Oviedo Convention, 1997.
- The Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research, 2005, Council of Europe Treaty Series No. 195.
- World Medical Association's Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Participants.
- Explanatory Report to the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research (2005).
- Explanatory Report to the Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (1997).
- Medicinal Products Act (Arzneimittelgesetz – AMG).
- Ethical considerations for clinical trials on medicinal products conducted with minors – Recommendations of the expert group on clinical trials for implementation of Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, 18 September 2017.

Websites:

- World Health Organization
- Oviedo Convention and its Protocols

- European Medicines Agency
- EMA's Paediatric Committee (PDCO)
- International Clinical Trials Registry Platform (ICTRP)
- UKRI: Involving Children in Research
- National Health System UK

Articles and Magazines:

- Rosato J., The Ethics of Clinical Trials: A Child's view. Journal of Law, Medicine & Ethics. 2000;28(4):362-378.
- Arenas-López S, Fajardo C, Valls i Soler A, García-Corzo JR, Lima-Rogel MV, Calle G, Leite R, Lobos E, Hume-Wright Q, MacLeod S., Pediatric clinical trials in Latin America and Guyana: present views of local practitioners and ways to embrace the future. Paediatr Drugs. 2011 Aug 1;13(4):257-65.
- Lepola P, Needham A, Mendum J, *et al*, Informed consent for paediatric clinical trials in Europe. Archives of Disease in Childhood 2016;101**:**1017-1025.
- Buchner B, Hart D. Research with minors in Germany. Eur J Health Law. 2008 Jul;15(2):127-34.
- Cave E. Seen but not heard? Children in clinical trials. Law Rev. 2010 Winter;18(1):1-27.
- Nuffield Council on Bioethics (UK), Children and clinical research: ethical issues, March 2015.
- Tait AR, Voepel-Lewis T, Levine R., Using digital multimedia to improve parents' and children's understanding of clinical trials. Arch Dis Child. 2015 Jun;100(6):589-93.
- Bos W, Tromp K, Tibboel D, Pinxten W. Ethical aspects of clinical research with minors. Eur J Pediatr. 2013 Jul;172(7):859-66.
- Laventhal N, Tarini BA, Lantos J. Ethical issues in neonatal and pediatric clinical trials. Pediatr Clin North Am. 2012 Oct;59(5):1205-20.

Ανασκόπηση

Cross-Species Boundaries and Human Rights: Legal and Ethical Reflections on Xenotransplantation

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Abstract

Xenotransplantation, i.e. the transplantation of cells, tissues, or organs derived from animals into humans—stands at the forefront of biomedical innovation, offering a promising solution to the persistent shortage of human donor organs. As this field advances rapidly, it simultaneously raises complex scientific, ethical, and legal challenges that demand careful consideration. The responsibility to safeguard animal welfare while ensuring human health protection is paramount, particularly given the zoonotic risks inherent in xenotransplantation research. Preclinical studies must rigorously address the potential for transmission of infectious agents from animals to humans, requiring robust risk assessment and management strategies that protect not only individual patients but also public health at large. Balancing these concerns with the imperative to develop life-saving therapies underscores the vital role of scientific responsibility.

Ethical questions surrounding xenotransplantation go beyond traditional biomedical concerns, probing deeply into the boundaries between species and what it means to be human. The creation and use of chimeras and hybrids challenge established concepts of identity, raising questions about the moral status of these entities and the ethical limits of scientific intervention. Patient rights remain central in this discourse, especially regarding informed consent, compassionate use of experimental treatments, and the equitable distribution of scarce organs. These issues compel ongoing reflection on autonomy, justice, and societal values, highlighting the need for ethical frameworks that can guide clinical practice and research in this emerging field.

At the same time, xenotransplantation operates within a diverse and evolving global legal landscape. Regulatory frameworks vary considerably across countries, reflecting different cultural, ethical, and political priorities. International organizations such as the International Xenotransplantation Association (IXA) and the World Health Organization (WHO) play critical roles in shaping policies, offering guidance, and promoting harmonization to facilitate responsible development and safe clinical application. Navigating this complex regulatory environment is essential for researchers and clinicians, who must comply with multifaceted requirements to ensure the ethical conduct of clinical trials and patient safety.

This article integrates scientific, ethical, and legal perspectives to provide a comprehensive overview of the current state and future prospects of xenotransplantation. It emphasizes the importance of an interdisciplinary approach that promotes innovation while rigorously addressing risks and respecting both

animal welfare and human dignity. By fostering collaboration among scientists, ethicists, policymakers, and healthcare providers, the xenotransplantation field can advance responsibly, ultimately transforming the landscape of transplantation medicine and offering new hope to patients facing organ failure worldwide.

Keywords: xenotransplantation; organ shortage, regulation; clinical trials; animal welfare.

Όρια μεταξύ ειδών και ανθρώπινα δικαιώματα: Νομικές και ηθικές σκέψεις για την ξενομεταμόσχευση

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Περίληψη

Η ξενομεταμόσχευση—η μεταμόσχευση κυττάρων, ιστών ή οργάνων προερχόμενων από ζώα σε ανθρώπους—αποτελεί την αιχμή της βιοϊατρικής καινοτομίας, προσφέροντας μια πολλά υποσχόμενη λύση στην επίμονη έλλειψη ανθρώπινων μοσχευμάτων παγκοσμίως. Καθώς ο τομέας αυτός εξελίσσεται ραγδαία, προκύπτουν παράλληλα πολύπλοκες επιστημονικές, ηθικές και νομικές προκλήσεις που απαιτούν προσεκτική εξέταση. Η ευθύνη για την προστασία της ευζωίας των ζώων και την ασφάλεια της ανθρώπινης υγείας είναι υψίστης σημασίας, ιδίως λόγω των ζωονόσων που ενυπάρχουν στην έρευνα ξενομεταμόσχευσης. Οι προκλινικές μελέτες πρέπει να αντιμετωπίζουν αυστηρά τον κίνδυνο μετάδοσης λοιμωδών παραγόντων από τα ζώα στους ανθρώπους, εφαρμόζοντας αξιόπιστες στρατηγικές αξιολόγησης και διαχείρισης κινδύνου που προστατεύουν όχι μόνο τους μεμονωμένους ασθενείς αλλά και τη δημόσια υγεία συνολικά. Η ισορροπία ανάμεσα σε αυτούς τους προβληματισμούς και την ανάγκη ανάπτυξης σωτήριων θεραπειών υπογραμμίζει τον κρίσιμο ρόλο της επιστημονικής ευθύνης.

Τα ηθικά ζητήματα που σχετίζονται με την ξενομεταμόσχευση υπερβαίνουν τις παραδοσιακές βιοϊατρικές ανησυχίες, εξετάζοντας βαθιά τα όρια μεταξύ των ειδών και το τι σημαίνει να είσαι άνθρωπος. Η δημιουργία και χρήση χιμαιρών και υβριδίων προκαλεί αμφιβολίες σχετικά με την ηθική κατάσταση αυτών των οντοτήτων και τα όρια της επιστημονικής παρέμβασης. Τα δικαιώματα των ασθενών παραμένουν κεντρικά σε αυτόν τον διάλογο, ειδικά όσον αφορά τη γνώση και τη συγκατάθεση, τη χρήση πειραματικών θεραπειών με συμπόνια και τη δίκαιη κατανομή των σπάνιων οργάνων. Αυτά τα ζητήματα απαιτούν συνεχή προβληματισμό για την αυτονομία, τη δικαιοσύνη και τις κοινωνικές αξίες, υπογραμμίζοντας την ανάγκη ηθικών πλαισίων που καθοδηγούν την κλινική πρακτική και την έρευνα σε αυτόν τον αναδυόμενο τομέα.

Παράλληλα, η ξενομεταμόσχευση λειτουργεί εντός ενός διαφοροποιημένου και εξελισσόμενου παγκόσμιου νομικού πλαισίου. Τα ρυθμιστικά πλαίσια ποικίλλουν σημαντικά ανάλογα με τη χώρα, αντανακλώντας διαφορετικές πολιτισμικές, ηθικές και πολιτικές προτεραιότητες. Διεθνείς οργανισμοί όπως η Διεθνής Ένωση Ξενομεταμόσχευσης και ο Παγκόσμιος Οργανισμός Υγείας (ΠΟΥ) διαδραματίζουν κρίσιμο ρόλο στη διαμόρφωση πολιτικών, την παροχή καθοδήγησης και την προώθηση της εναρμόνισης των προτύπων για την υπεύθυνη ανάπτυξη και ασφαλή κλινική εφαρμογή. Η πλοήγηση σε αυτό το σύνθετο ρυθμιστικό περιβάλλον είναι απαραίτητη για τους ερευνητές και τους κλινικούς ιατρούς, που πρέπει να συμμορφώνονται με πολυδιάστατες απαιτήσεις για να διασφαλίσουν την ηθική διεξαγωγή των κλινικών δοκιμών και την ασφάλεια των ασθενών.

Το άρθρο αυτό συνδυάζει επιστημονικές, ηθικές και νομικές προσεγγίσεις, προσφέροντας μια ολοκληρωμένη επισκόπηση της τρέχουσας κατάστασης και των μελλοντικών προοπτικών της ξενομεταμόσχευσης. Τονίζει τη σημασία μιας διεπιστημονικής προσέγγισης που προωθεί την καινοτομία, ενώ ταυτόχρονα αντιμετωπίζει με αυστηρότητα τους κινδύνους και σέβεται τόσο την ευζωία των ζώων όσο και την ανθρώπινη αξιοπρέπεια. Με την προώθηση της συνεργασίας μεταξύ επιστημόνων, ηθικολόγων, νομοθετών και επαγγελματιών υγείας, ο τομέας της ξενομεταμόσχευσης μπορεί να εξελιχθεί

υπεύθυνα, προσφέροντας τελικά νέες ελπίδες σε ασθενείς που αντιμετωπίζουν ανεπάρκεια οργάνων παγκοσμίως.

Λέξεις κλειδιά: ξενομεταμόσχευση; έλλειψη οργάνων; κανονισμοί; κλινικές δοκιμές; ευζωία ζώων.

Introduction

Xenotransplantation: Concepts and Latest Advancements

Advancements in transplantation procedures are paving the way for allowing medical professionals to perform xenotransplantation. This identifies the transplantation of an organ or tissue within two individuals belonging to different species, where the transplanted body part is called a xenograft. The Food & Drug Administration (FDA) defines xenotransplantation as "any procedure that involves the transplantation, implantation or infusion into a human recipient of either a) living cells, tissues or organs from a non-human animal source or b) human body fluids, cells, tissues or organs that have had ex vivo contact with live nonhuman animal cells, tissues or organs".1 Xenotransplantation encompasses both animal-to-animal and animal-to-human procedures. Although it remains a relatively recent area of interest compared to the most known allotransplantation, xenotransplantation—particularly animal-to-human procedures—has already yielded promising early results.

Within the scientific community, pigs are widely regarded as the most suitable donors for genetically modified organs, primarily due to the anatomical compatibility of their organs with those of humans, as well as their rapid reproductive cycles and ability to produce multiple offspring per pregnancy. At present, the organs most commonly considered for xenografting are kidneys, hearts, and the thymus gland, which is often transplanted together with the kidney to support immune compatibility.

In terms of heart transplantation, a landmark procedure was performed in January 2022, when the first gene-edited pig heart was transplanted into a human patient.[2] Unfortunately, the patient died two months later due to a porcine virus infecting the graft.[3] The following year, in 2023, a second similar transplant was attempted, but the graft was ultimately rejected, and the recipient passed away.[4]

Kidney xenotransplantation has shown more stable outcomes so far. In 2023, a genetically modified pig kidney was transplanted into a brain-dead man and later safely removed, marking a significant step forward in testing feasibility and safety.5 In 2024, the first living recipient of a modified pig kidney was reported; although the patient later passed away, the cause of death was unrelated to the transplant itself.6 Around the same period, a gene-edited pig kidney and thymus gland were transplanted into a living woman who was also supported by a mechanical heart pump. The graft remained viable and performed effectively for forty-seven days before being removed due to complications arising from the patient's pre-existing cardiovascular condition. She later died from said unrelated health issues.7 Most recently, on January 25th, 2025, a gene-edited pig kidney was transplanted into a human as part of a three-

1 U.S. Food and Drug Administration, *Xenotransplantation.*

2 The Guardian, *Maryland man receives pig's heart in world-first transplant.*
3 The Guardian, *Man who had landmark pig heart transplant dies after pig virus infection.*
4 CNN, *Lawrence Faucette, second person to receive pig heart transplant, dies.*
5 CNN, *Pig kidney successfully functions in human for over a month.*
6 CNN, *Pig kidney transplant patient discharged and recovering at home.*
7 CNN, *Woman is back on dialysis after doctors remove transplanted pig kidney.*

person clinical study, further advancing clinical research in this emerging field.8

These experimental procedures demonstrate not only scientific progress but also the increasing feasibility of xenotransplantation as a therapeutic option. However, they also underscore the importance of continued monitoring, refinement of genetic modifications, and rigorous ethical and clinical oversight to ensure long-term safety and effectiveness.

1. Animal Welfare, Zoonotic Risk, and Human Health: A Scientific Responsibility

Preclinical Research and Animal Welfare

Initially, preclinical xenotransplantation studies were carried out primarily between non-human species, serving as essential models for advancing scientific understanding while avoiding the ethical complexities of human trials. Today, these studies are governed by strict international regulations designed to ensure that scientific progress does not come at the expense of animal welfare. In Europe, this balance is articulated through Directive 2010/63/EU, which sets a comprehensive ethical framework for the use of animals in scientific research.

Central to this directive are the principles of replacement, reduction, and refinement—the "3Rs"—which guide researchers toward minimizing animal use and suffering. Scientific justification is now a prerequisite for any study involving animals, and approval must be obtained from competent authorities before experiments can begin. Rather than allowing open-ended or excessive animal use, researchers are required to carefully design their studies to involve only the minimum number of animals necessary to achieve reliable results. Moreover, the directive emphasizes not just the quantity but the quality of animal care. It mandates that any potential pain or distress be reduced to the lowest possible level through refined procedures and humane practices. Animals must be housed in environments tailored to their species-specific needs, with adequate space, enrichment, and opportunities for social interaction—all of which are critical to their well-being and to the reliability of scientific data. Importantly, the directive recognizes that ethical research also depends on the professionals conducting it. For this reason, it requires that all personnel involved be properly trained in both scientific techniques and animal welfare. Veterinary care must always be available, and clear humane endpoints must be set to prevent unnecessary animal suffering. These requirements reflect a commitment to advancing science responsibly and with respect for animal life.

In the United States (US), preclinical xenotransplantation research is primarily overseen by the U.S. FDA, operating under the authority of the Public Health Service Act and the Federal Food, Drug and Cosmetic Act. Xenotransplantation products are classified as biological products, meaning they must undergo the FDA's Investigational New Drug (IND) application process before entering clinical trials. This regulatory framework is designed not only to ensure rigorous safety evaluations but also to uphold strong ethical standards throughout the research process.

Central to the FDA's oversight are its xenotransplantation guidelines, which mandate that animal testing be scientifically justified, ethically reviewed, and supported by thorough risk assessments. These guidelines emphasize the selection of the least sentient animal species capable of yielding valid data, in line with broader ethical considerations. Additionally, researchers must provide detailed documentation regarding animal housing, nutrition, and care, ensure regular veterinary supervision, and define humane endpoints to minimize suffering. The guidelines also extend beyond animal welfare to include biosafety, requiring evaluation of potential zoonotic risks and the implementation of

8 CNN, *Pig kidney transplant patient discharged and recovering at home.*

environmental safety measures. As the research advances toward human trials, informed consent procedures must be comprehensive and transparent, particularly concerning the animal origin of the treatment and any associated risks.[9]

Beyond these foundational requirements, recent shifts in U.S. regulatory policy signal a broader transformation in the approach to preclinical research. In 2025, the FDA announced a phased transition toward New Approach Methodologies (NAMs)—innovative alternatives such as computational modeling and lab-grown human tissues. These emerging tools aim to reduce reliance on animal models while enhancing scientific precision and aligning with international efforts to adopt more humane, sustainable research practices.[10] Together, these regulatory measures and evolving policies demonstrate a commitment not only to ensuring the safety and efficacy of xenotransplantation but also to advancing a more ethical approaches for biomedical research.

These preliminary studies serve to test basic feasibility, immune responses, and organ compatibility in xenotransplantation. As the research progresses, subsequent phases typically involve non-human primates as recipients because their physiological and immunological systems closely resemble those of humans. This step is crucial as it allows researchers to more accurately predict potential outcomes and identify safety concerns that may arise in future human clinical trials, thereby improving the likelihood of success and patient safety.

Safety: Managing Infectious Risk for Human Health

Managing infectious risks in xenotransplantation is a critical and multifaceted challenge that requires stringent oversight and constant innovation.11 One major concern involves the health status of recipients: patients with multiple comorbidities are at increased risk of complications post-transplant, whereas those with isolated organ failure tend to have higher survival rates.12 A key risk in this context is xenozoonosis—the transmission of infectious agents, particularly retroviruses, from animals to humans. Although advances in genetic engineering have enabled the breeding of pathogen-free source animals, the threat persists, especially when pathogens remain undetectable during pre-transplant screening.13 Consequently, recipients

9 U.S. Food and Drug Administration, *Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans; Guidance for Industry*, CBER, 13.12.2016; U.S. Department of Health and Human Services, *PHS Guideline on Infectious Disease Issues in Xenotransplantation*, 19.1.2001 (updated 23.6.2022).

10 FDA, Roadmap to Reducing Animal Testing in Preclinical Safety Studies; Reuters, *US FDA to phase out animal testing in drug development.*

11 Public Health Service PHS Guideline on Infectious Disease Issues in Xenotransplantation, 19.1.2001, updated 23.6.2022;

12 Sorror MA, et al. Influence of comorbidities on outcome in 1102 patients with acute myeloid leukemia undergoing allogeneic hematopoietic cell transplantation. *Bone Marrow Transplant* 2024, 59: 115–123;

13 Denner J, Tönjes RR. Infection barriers to successful xenotransplantation focusing on porcine endogenous retroviruses. Clin Microbiol Rev 2012, 25: 318-343; Meije Y, Tönjes RR, Fishman JA. Retroviral restriction factors and infectious risk in xenotransplantation. Am J Transplant 2010, 10: 1240-1247.

must consent to lifelong monitoring and may face restrictions on movement, which can extend to family members and close contacts. To guide prevention and management strategies, expert recommendations—such as those from the Infectious Disease Community of Practice of the American Society of Transplantation—provide protocols for identifying, assessing, and mitigating infectious disease risks, particularly in trials involving swine-derived grafts.14

Effective risk management also depends on robust regulatory and procedural frameworks. The FDA outlines specific criteria for the selection and maintenance of source animals, including breeding in closed colonies, microbiological screening to exclude pathogens dangerous to humans or immunocompromised individuals, environmental surveillance, and the storage of biological samples for future testing. Of particular concern are pathogens with long incubation periods that may go undetected at the time of transplantation.

In parallel, pharmacovigilance must be integrated from the preclinical phase onward, following its core components: detection, assessment, understanding, and prevention of adverse effects. Implementing these systems early allows for timely identification and response to risks affecting both animal models and potential human recipients, thereby preserving the integrity of xenotransplantation trials. Oversight of these trials must be carried out by institutional review boards and research ethics committees, which—though not necessarily state-run—must be independent, publicly recognized bodies with the authority to evaluate protocols comprehensively. Their responsibilities include preemptive scientific and ethical assessments, continuous monitoring, and ensuring compliance with established timelines and standards. Benchmarking their evaluations against internationally accepted best practices helps ensure that xenotransplantation research proceeds safely, ethically, and transparently, with a clear commitment to protecting individual and public health.

In early 2025, a biotech company called United Therapeutics announced that it had received the green light from the FDA for its gene-edited pig kidneys trial, with plans to perform six transplants by the summer and with the ambicious intent of reaching the number of fifty patients.[15]

2. The Ethics of Crossing Boundaries: Animal Use, Human Identity, and Patient Rights

Ethical Issues in Animal-Based Trials

Beyond assessing clinical efficacy, both preclinical and clinical xenotransplantation trials must be firmly grounded in comprehensive ethical evaluation. This ethical scrutiny extends beyond the scientific justification for using animal models, encompassing the standards of care, housing, and overall welfare provided to research animals. Ensuring humane treatment involves routine

14 Mehta SA, Saharia KK, Nellore A, Blumberg EA, Fishman JA. Infection and clinical xenotransplantation: Guidance from the Infectious Disease Community of Practice of the American Society of Transplantation. *Am J Transplant* 2023, 23(3): 309–315.

15 United Therapeutics Corporation. *FDA clearance of Investigational New Drug application for UKidney™ clinical trial*. 3.2.2025; Healey N. *World-first pig kidney trials mark turning point for xenotransplantation*. Nature Medicine, 18.3.2025; *We need this*: Pig-to-human kidney transplants enter clinical trials, Healio, 27.6.2025; Successful pig-to-human xenotransplant paves the way for clinical trials. Kidney News, 27.6.2025.

environmental monitoring, appropriate living conditions for laboratory herds, individualized risk assessments, and attention to the broader public health implications of such research. These considerations reflect the complex nature of ethics in xenotransplantation.

Philosopher Bernard Rollin's concept of minimal moral standing is particularly relevant in this context. According to this principle, animals bred specifically for research purposes—such as those used in xenotransplantation—are entitled to a basic level of moral consideration. This implies a duty to minimize their suffering, promote their welfare, and treat them humanely, even within the constraints of scientific investigation. It also involves the use of enriched environments, the least invasive procedures possible, and a broader respect for the sentience of these animals.[16]

However, this raises a deeper ethical tension: while animals do not possess legal rights and are protected primarily through welfare standards rather than rights-based frameworks, we often apply human-centered concepts of "humane treatment" to their care. It is therefore questionable whether it is truly appropriate or sufficient to impose standards derived from human ethics onto beings that lack legal personhood. Moreover, in the context of xenotransplantation, many animals are bred and kept alive explicitly for utilitarian purposes. As such, animals are utilized as subordinated beings relative to humans, precisely because of their instrumental role in clinical trials. The notion of treating these animals "humanely" often reflects a minimal ethical concession that does not fully address the fundamental moral conflicts inherent in their use.

Ethically, it cannot be overlooked that animals intrinsically may have the potential to be recognized as rights holders, and not merely subjects of welfare considerations. This perspective invites reflection on whether it is conceivable to envision a future in which animals are granted legal rights that would exclude their use in clinical trials. Such a shift could encourage the development and preferential use of laboratory-created beings with utilitarian purposes, potentially redefining the ethical landscape of biomedical research.

Ethical and Societal Perspectives on Chimeras and Hybrids

Expanding on ethical concerns about using animals in trials, the creation of hybrids and chimeras presents a complex alternative that challenges traditional boundaries and sparks new debates in ethics, law, and science. Being a combination of human and non-human DNA, hybrids and chimeras are among the most controversial topics in bioethics, raising questions about the boundaries of human identity. Although definitions remain debated, both terms have recognizable features: a hybrid typically results from combining a human cell nucleus with an animal egg, while a chimera involves the coexistence of human and animal cells within the same organism, often from early embryonic fusion. This definitional ambiguity complicates regulatory frameworks and ethical interpretation.[17] The EU-funded CHIMBRIDS project extends the definition further, suggesting that simply hosting cells from two organisms in one body qualifies as a

16 Rollin B, *Animal Rights and Human Morality*, 1st ed, Prometheus Books, Buffalo, New York.

17 Bokota S. *Defining human-animal chimeras and hybrids: A comparison of legal systems and natural sciences*, Ethics & Bioethics (in Central Europe) 2021, 11(1–2): 101–114.

chimera—raising regulatory concerns if, for instance, heterograft recipients are included.[18]

A related development is human embryoids, created from pluripotent stem cells to model embryo-like growth.[19] Though promising for research, they intensify the need for regulatory standardization. The EU allows in vitro research with no intent of implantation,[20] while in vivo development is largely prohibited due to risks to human dignity. Implanting such embryos—whether into an animal or human womb—is the most controversial aspect, with artificial wombs potentially offering a less ethically problematic alternative. Hybrids and chimeras could provide a limitless source of cells and tissues for transplantation and regenerative therapies. Genetic engineering allows scientists to create these organisms in vitro and derive embryonic stem cells, useful for studying mutations, developing therapies for diseases such as neurodegenerative diseases, and advancing personalized medicine. Still, ethical concerns persist, especially regarding the potential of therapeutic human cloning, with most arguments currently weighing against it.

While in vitro development with no implantation may not violate human dignity, the in vivo transfer raises questions of both human and animal welfare. Given that hybrids and chimeras contain human genetic material, their moral status is debated. Even if not violating human dignity directly, their creation could challenge the integrity and protection of animals. Though "animal dignity" is not a legally recognized concept, it is increasingly discussed through the lens of animal welfare.

If such beings were born, their legal and moral classification would present new ethical challenges. It would be necessary to consider whether they should be recognized as persons or if a new legal and moral status should be created for them. Central to this debate are questions of language, identity, cognitive ability, and appearance. The choice of pronouns—using “he” or “she” instead of “it”—reflects a broader societal discussion on how value and identity are attributed. The ability to self-determine might serve as one possible standard for personhood; however, many humans, such as those with severe physical or mental disabilities, are fully recognized members of society despite lacking self-determination. Applying this criterion exclusively to hybrids would therefore be discriminatory. Appearance further complicates the matter, since a being that looks more human may be more socially accepted, even with limited autonomy, while a being with greater cognitive capacities but more animal-like features might not receive the same recognition. Assigning legal and moral status to hybrids and chimeras challenges current ethical frameworks, which may need to be rethought based on multiple values—including appearance, genetic proximity, and cognition—rather than a single criterion. The underlying issue involves not only how these beings would exist biologically, but also how they would be perceived socially and legally in a world centered on humans.

Consent, Compassionate Use, and Organ Distribution: Ethical Reflections on Patient Autonomy

Informed consent, the right to withdraw, moral dissent, and the balance between individual autonomy and collective welfare are central concerns. Although organ allocation is primarily governed by law, ethical and psychosocial

18 Cordis, *EU funds project on chimera and hybrid research*. 19.6.2007.

19 Iltis AS, Koster G, Reeves E, Matthews KRW. Ethical, legal, regulatory, and policy issues concerning embryoids: a systematic review of the literature. *Stem Cell Research & Therapy* 2022, 13(1): 1–13; Nicolas P, Etoc F, Brivanlou AH. The ethics of human-embryoids model: a call for consistency. *Journal of Molecular Medicine* 2021, 99(4): 569–579.

20 European Parliament, Council of Europe, Use of human embryos and foetuses in scientific research, Recommendation 1100 (1989); Council of the European Union. *Council adopts new rules on substances of human origin*. 27.5.2024.

evaluations play a crucial role in determining eligibility, aiming to prioritize not only those without alternatives but also those likely to benefit significantly in terms of quality of life.

In standard allotransplantation procedures, organ distribution is grounded in three foundational principles: justice, medical utility, and respect for persons.[21] The principle of justice relates to fairness in both the distribution of organs and the evaluation of candidates. Key factors include medical urgency, time on the waiting list, compatibility likelihood, age, and geographical proximity to the donor hospital. In addition, whether the patient is undergoing a first or repeat transplant is also ethically relevant. The principle of medical utility encompasses both objective and subjective dimensions. Objectively, it seeks to maximize the total number of successful transplants performed. Subjectively, it evaluates the recipient's post-transplant life expectancy, integrating considerations of quality and length of life. This principle intersects with concepts from health economics, particularly cost-utility analysis, which incorporates both the *beneficence* of prolonging life and the *non-maleficence* of avoiding harm. It also aligns with utilitarian ethics, which prioritize outcomes and aim to maximize overall benefit.[22] The third principle, respect for persons, reflects the obligation to treat individuals as ends in themselves. This includes upholding their autonomy, valuing their informed preferences, and enabling meaningful self-determination in medical decision-making. These ethical principles are already embedded in allotransplantation systems and should be extended to guide xenotransplantation practices. However, new ethical tensions may emerge, raising the question of whether additional or modified principles are needed.

For instance, when a xenograft represents the only medically viable option for a given patient, its use may be ethically justified under principles of beneficence and medical necessity. This scenario opens to broader ethical considerations surrounding the compassionate use of medical treatments that are still experimental or under clinical trial. While it may offer hope to patients in critical conditions, it also raises complex questions about risk-benefit assessment, informed consent, regulatory oversight, and equity of access. In the case of xenotransplantation, its potential use under compassionate grounds requires careful ethical scrutiny, particularly given the uncertainties surrounding safety, efficacy, and long-term outcomes. Equally important is the psychological and emotional condition of the patient. Facing a life-threatening illness, an individual might feel compelled to accept a highly experimental and invasive procedure out of desperation, even when the expected benefits are marginal. In such cases, it becomes necessary to question whether the patient's consent is truly autonomous or merely the product of fear and limited options. This calls for the careful involvement of ethics committees and

21 OPTN Ethics Committee. Ethical Principles in the Allocation of Human Organs. IntechOpen, 2019: 3-10; National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, 1979.

22 National Institute for Health and Care Excellence (NICE). *Glossary: Utility*.; Organ Procurement and Transplantation Network (OPTN), *Ethical Principles in the Allocation of Human Organs.*

the implementation of psychological assessments tailored to the patient's situation.

The issue of consent becomes even more complex when considering the use of brain-dead individuals in early xenotransplantation procedures. A brain-dead individual cannot, by definition, provide contemporaneous informed consent. Therefore, the process must rely on prior expressions of will. The most formal mechanism is the use of advance directives, which—depending on the jurisdiction—may or may not be legally binding. Even where such directives exist, healthcare providers are not necessarily obligated to follow them if the procedure is deemed non-beneficial. In such cases, the legal representative is tasked with acting in the patient's best interest. It is ethically preferable that consent for such an intervention be obtained from a fully competent and alert patient, capable of making an informed decision based on clear medical advice. Yet, when the prospect of survival is extremely limited, patients or their families may accept high-risk procedures in hopes of even brief life extension. Ethical, psychological, and medical evaluations are therefore essential to ensure that decisions are made responsibly and without coercion. In some situations, patients may have informally expressed their willingness to participate in experimental treatments. While ethically relevant, such informal statements are often not legally binding. As a result, healthcare providers and legal representatives may hesitate to act on them, especially in high-risk contexts. When no preferences are known, proceeding with experimental xenotransplantation in a brain-dead individual raises serious ethical and legal challenges. In jurisdictions where diminished autonomy still carries legal protections, such interventions could be seen as involuntary medical treatment, violating both ethical and human rights standards. There is, however, one scenario in which the use of xenografts in brain-dead patients may be ethically defensible: when used to sustain organ function temporarily for the purpose of allograft donation. In these cases, a xenograft could preserve the viability of transplantable organs until they are retrieved for recipients. If the deceased had previously consented to organ donation and to extraordinary measures to support that intention, the temporary use of xenografts could be considered consistent with their wishes. This approach mirrors current practices in allotransplantation, where life-support is maintained post-mortem until the donation process is complete.

The possibility of choosing between an allograft and a xenograft raises further ethical considerations, particularly in relation to patient perception and preference. While xenografts—especially those derived from genetically modified animals—may be clinically equivalent to human allografts, their animal origin could carry significant psychological, cultural, or ethical implications for some patients. This potential reluctance raises the question of whether it might be ethically permissible—or even advisable—to introduce forms of incentive or compensation to encourage acceptance of xenografts. Such a strategy should be designed to guarantee patient autonomy, avoiding undue inducement.

Throughout the selection process, additional factors may influence eligibility. These include the patient’s behavioral reliability, such as the absence of a history of recklessness or negligence that could compromise adherence to clinical protocols. Infact, beyond initial consent, the right to withdraw consent before or after the procedure warrants careful evaluation. Patients must be thoroughly informed by physicians about all potential outcomes and necessary steps to maintain control over the treatment process. It is important to clarify the boundary between patient autonomy and the physician’s responsibility. While patients cannot be forced to undergo the procedure without consent, withdrawing consent after implantation of the xenograft raises complex questions about which medical acts are being refused. If a patient demands graft removal, medical, psychological, and ethical evaluations are essential to navigate potential controversies. Moreover, the patient and their family must be willing to engage in continuous consultation before, during, and after the procedure, demonstrating a clear commitment to follow safety protocols and long-term treatment plans.

In allotransplantation, recipients are already required to adopt strict lifestyle modifications to protect both their health and the graft. Xenotransplantation introduces an additional layer of complexity: the potential risk to public health.

This elevates the ethical stakes, requiring even stricter adherence to safety protocols and raising the controversial possibility of using background checks to assess a patient's likely compliance. While such evaluations might seem justified by the need to prevent harm, they raise serious ethical concerns. They risk infringing on human dignity by relying on assumptions that past behavior determines future conduct, which could unfairly exclude individuals from accessing potentially life-saving treatment. Such exclusions may ultimately amount to discrimination, undermining the principle of equal access to care.

3. *Xenotransplantation and Legal Diversity: Navigating Global Regulatory Landscapes*

The Role of IXA and WHO in Shaping Xenotransplantation Governance

State's regulations on the topic of xenotransplantation have been particularly fragmented and haven't addressed every side of the issue in an holistic way. Undoubtedly, WHO has played a crucial role on the development of the topic of xenotransplantation, together with other international entities such as the IXA and the Transplantation Society. Their combined contribution has been considered the common ground on which state's regulations have been standing. However, standardization is a priority that is now taking nearly two decades to develop. Legally speaking, the topic is addressed both directly and indirectly by soft law sources, as well as guidelines and regulations. It is interesting to assess how IXA and WHO contribution intersected troughout the years and also trace the key milestones that have shaped the discourse on xenotransplantation over the years.

In 2003, IXA's Ethics Committee published a contribution aimed to point out requirements of adequate preclinical data, as well as proper oversight by competent authorities and approval by specific institutional bodies in charge of ethical overseeing over human research and animal welfare.[23]

In 2001 and 2004, the WHO called on the international community to address the risks associated with xenotransplantation by publishing the *Guidance on Xenogenic Infection/Disease Surveillance and Response*.[24] This document aimed to promote debate and foster coordination and cooperation on a global scale. It emphasized the need for regulation to prevent zoonotic infections and highlighted the importance of surveillance through data collection, registries, and effective communication within a multi-level international network. Notably, the annexes include a glossary, sample forms and reports, and indicators for evaluating the network. While the Guidance sought to promote harmonized regulation, a global standardization of practices remains urgently needed to ensure safety, ethical consistency, and legal clarity.[25]

23 Sykes M, d'Apice A, Sandrin M; IXA Ethics Committee. Position paper of the Ethics Committee of the International Xenotransplantation Association. Xenotransplantation 2003, 10: 194-203; Menell J, Allison M, Wolf L. Regulatory aspects of clinical xenotransplantation. *Xenotransplantation* 2015, 22:?205-13.

24 World Health Organization, *Guidance on Xenogeneic Infection/Disease Surveillance and Response: a strategy for international cooperation and coordination*, WHO, Geneva, 2001.

25 WHO. Guidance on Xenogeneic Infection/Disease Surveillance and Response: A

In 2008, the WHO, together with the IXA, the Chinese Ministry of Health, and the University of South China, launched a global consultation on clinical xenotransplantation. This collaboration produced three key documents (2008, 2011, 2018) shaping international ethical and regulatory guidelines. The 2008 consultation outlined general principles and specific recommendations for WHO, Member States, and researchers.[26] It recognized xenotransplantation as a potential solution to organ shortages but emphasized strict controls, thorough scientific and ethical review, public engagement, lifelong patient monitoring, and international data sharing. WHO was urged to coordinate global efforts and infectious risk management. Member States were encouraged to regulate and inform the public, banning unsafe practices if necessary. Investigators had to ensure biosafety, provide solid trial justifications, and plan long-term follow-up. Patient selection required no alternative treatments and fully informed, compliant candidates.

The 2011 consultation had three primary objectives: to review the current state of science and clinical practice in xenotransplantation, to assess the need for revisions to existing guidance, and to refine strategies for the surveillance, prevention, and management of infectious risks.[27] A key concern was the persistence of unregulated trials, some of which had disregarded previous recommendations. While the principles laid out in 2008 were reaffirmed as sufficient to protect public health, this second consultation reinforced the urgency for the WHO to promote ongoing international collaboration, transparency, and periodic reassessment of practices. It also recommended that Member States, sponsors, and investigators pursue greater consistency with best available standards, address misinformation, and rely on independent, experienced laboratories to ensure quality and credibility. Overall, this second phase maintained continuity with the initial framework, while encouraging improvements in clinical trial design and promoting a more integrated, globally coordinated approach to xenotransplantation.

The 2018 consultation marked the third and most technical iteration of this global process.[28] Its primary goal was to revisit the scientific and regulatory status of xenotransplantation and to update consensus-based recommendations for infectious disease control in preparation for upcoming trials. The 2018 consultation was organized into expert panels and six specialized working groups, which revised and expanded the "Principles and Recommendations" of the original Consultation. These groups covered a wide range of topics, including xenozoonosis, regulatory frameworks, biorepositories, genetically modified pig facilities, biomaterials, and immunosuppression strategies. Key discussions addressed emerging issues such as new technologies in gene editing, donor animal herd management, legal developments across jurisdictions, and practical

Strategy for International Cooperation and Coordination.

26 World Health Organization, *First WHO global consultation on regulatory requirements for xenotransplantation clinical trials, Changsha, China, 19–21 November?2008: the Changsha Communiqué*, WHO, Geneva, 2008.

27 World Health Organization, *Second WHO Global Consultation on Regulatory Requirements for Xenotransplantation Clinical Trials*, Geneva, 2011.

28 World Health Organization, Third *WHO Global Consultation on Regulatory Requirements for Xenotransplantation Clinical Trials*, Geneva, 2018.

aspects of trial applications. Particular attention was given to developing protocols for xenotransplantation of islet cells, corneas, and kidneys. During the consultation, progress in cell and tissue xenotransplantation was discussed, highlighting the move toward early-phase clinical trials and emphasizing core ethical standards such as respect for persons, beneficence, justice, lack of alternative treatments, justified immunosuppression, strong preclinical evidence, community safety, and rigorous donor animal biosecurity. The infrastructure and microbiological controls for genetically modified pigs were reviewed, showcasing facilities in several countries. Regulatory frameworks were clarified, including definitions of xenotransplantation products and oversight pathways that vary based on product type and development stage, with particular attention to the risks of genetically modified donor animals. Public health emergency reporting, disease surveillance, and recipient monitoring systems were also covered, along with discussion of specific viral infections and the introduction of Prevymis, a novel antiviral drug in development at that time.

Overall, these three consultations laid a foundation for the ethical and legal governance of xenotransplantation at the global level. While the 2008 consultation provided a conceptual and regulatory baseline, the 2011 and 2018 meetings progressively expanded the technical depth and scope of guidance, reflecting the evolving scientific landscape and reinforcing the need for coordinated international standards to ensure both patient safety and ethical integrity.

Regulatory Sources Overview

In the US, the main regulatory bodies overseeing xenotransplantation are the FDA and the Centers for Medicare and Medicaid Services. The FDA offers various online resources related to xenotransplantation, including two key Guidance documents from the Center for Biologics Evaluation and Research (CBER).[29] CBER's jurisdiction covers allergenics, blood and blood products, cellular and gene therapies, tissue-based products, vaccines, and xenotransplantation products. Notably, the FDA issued the Public Health Service Guidance "Infectious Disease Issues in Xenotransplantation" (2001) and the "Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans" Guidance for Industry (2016). Additionally, in 2009, the FDA released a Guidance for Industry titled "Heritable Intentional Genomic Alterations in Animals: Risk-Based Approach." The FDA also runs the Expanded Access Program, often called compassionate use, which allows patients with life-threatening conditions to access investigational medical products. Another important body is the Cellular, Tissue, and Gene Therapies Advisory Committee, which evaluates data on the safety, effectiveness, and appropriate use of human cells, tissues, gene therapies, and xenotransplantation products intended for transplantation, implantation, infusion, or gene transfer in disease treatment as well as tissue repair and reconstruction. FDA guidance on xenotransplantation regulates from initial considerations related to animal welfare and surveillance, to development to production of xenograft in the States, and also regulates related

29 Hawthorne WJ. Ethical and legislative advances in xenotransplantation for clinical translation: focusing on cardiac, kidney and islet cell xenotransplantation. *Front Immunol* 2024.

clinical investigations in the Country. On the other hand, the institutions like the Institutional Animal Care and Use Committee, on the other hand, regulate the side that has to do with animal welfare, from the selection, the housing in specialized facilities and the constant monitoring in order to prevent the spread of diseases and to guarantee the positive results of all phases of the procedure. Even sample storage holds its own differences throughout the Countries, since the US requires fifty years, whereas the UK requires thirty years.

Within the European Union, the European Medicines Agency (EMA) classifies xenogeneic cell therapy products as Advanced Therapy Medicinal Products (ATMP).[30] ATMPs are the focus of two Guidances, one on Gene Therapy medicinal products, the other one on Cell-therapy and tissue engineering. These fall under Regulation 1394/2007, which covers their authorization, supervision, pharmacovigilance, risk management, and addresses combination products. On the whole, clinical trials in the EU are regulated by Regulation No. 536/2014. In addition, several directives are relevant in this context: Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms; Directive 2001/83/EC on the Community code for medicinal products for human use; Directive 2001/20/EC on good clinical practice in the field of ATMPs; and Directive 2009/41/EC on the contained use of genetically modified microorganisms. Also applicable are Directive 2005/28/EC, concerning good clinical practice for investigational products and manufacturing/import authorization, and Directive 2006/86/EC, which implements Directive 2004/23/EC with respect to traceability requirements, notification of serious adverse reactions and events, and technical specifications for the coding, processing, preservation, storage, and distribution of human tissues and cells.

On the other hand, the Council of Europe's 2003 report on the state of the art in this field led to Recommendation (2003)10 which set out strict ethical and regulatory guidelines for xenotransplantation, urging a precautionary approach due to unknown infectious risks. It emphasized long-term recipient monitoring, animal welfare, and international cooperation. The text also reinforced the importance of informed consent and public health protection. Equally significant are the Declaration of Istanbul on Organ Trafficking and Transplant Tourism (2018), and the Convention on Human Rights and Biomedicine (Oviedo Convention, 1997), which addresses the protection of human rights and dignity in the application of biology and medicine.

In Switzerland, the Federal Law on the Transplantation of Organs, Tissues and Cells (2004), known as the Transplantation Act, explicitly includes grafts of animal origin in its definition of transplant products.[31] These are described as "products manufactured from human or animal organs, tissue or cells that can be standardized or whose manufacturing process can be standardized," and require authorization from the competent regulatory authority.

In China, the regulatory body responsible is the Chinese FDA. Organ donations saw a sharp decline after the World Medical Association (WMA) urged China to end the widespread practice of procuring

30 European Medicines Agency. *Advanced Therapy Medicinal Products: Overview*. EMA, London, 2025.

31 Swiss Confederation. Federal Act on the Transplantation of Organs, Tissues and Cells (Transplantation Act). Fedlex, 810.21, 1.7.2007.

organs from executed prisoners without consent—a practice that had long been the country's primary organ source. Its discontinuation significantly reduced the availability of organs for allotransplantation. Nevertheless, the Chinese public responded positively to the shortage, with the Red Cross Society of China reporting a notable rise in registered donors. At the same time, the People's Republic of China continues to explore xenotransplantation as a potential solution to its organ shortage.[32]

Conclusions

The advancements in xenotransplantation represent a significant breakthrough in addressing the critical shortage of human donor organs. Xenografts offer a promising solution by utilizing animals bred specifically for transplantation, providing a more abundant and readily available source of organs due to their rapid reproduction rates and biological similarities to humans. Genetic modifications, empowered by precise gene-editing tools such as CRISPR, are revolutionizing the transplant paradigm—shifting the focus from suppressing the recipient's immune system toward tailoring donor organs to improve compatibility, reduce rejection, and minimize risks such as retroviral infections.

These scientific achievements have already translated into notable clinical milestones, despite ongoing challenges like immune rejection and zoonotic risks. Furthermore, xenotransplantation may alleviate logistical hurdles in organ donation by maintaining essential bodily functions in recipients through xenografts, thereby increasing flexibility in organ procurement and potentially enhancing transplant success rates.

However, the promise of xenotransplantation also brings complex ethical and regulatory concerns. While expanding legal organ availability could reduce dependence on illicit organ markets and transplant tourism, there is a risk that unregulated xenotransplant clinics, particularly in regions with weaker oversight, could foster new forms of medical tourism linked to health risks and ethical violations. Thus, comprehensive and coordinated international regulatory frameworks are essential. Such frameworks should include rigorous monitoring of donor animal health, transparent eligibility criteria for recipients, and global governance mechanisms designed to safeguard patient safety, ensure equitable access, and prevent exploitation.

Moving forward, xenotransplantation requires continued interdisciplinary collaboration across genetic engineering, immunology, infectious disease control, ethics, and law. By integrating robust scientific innovation with ethical responsibility and regulatory vigilance, xenotransplantation has the potential not only to save countless lives but also to redefine the future of transplantation medicine and global health.

Bibliography

1 U.S. Food and Drug Administration, Xenotransplantation, available at: https://www.fda.gov/vaccines-blood-biologics/xenotransplantation?utm_source=chatgpt.com

2 The Guardian, Maryland man receives pig's heart in world-first transplant, available at: https://www.theguardian.com/us-news/2022/jan/10/maryland-pig-heart-transplant-human-medical-first

3 The Guardian, Man who had landmark pig heart transplant dies after pig virus infection, available at: https://www.theguardian.com/us-news/2022/may/06/man-landmark-pig-heart-transplant-death-pig-virus

4 CNN, Lawrence Faucette, second person to receive pig heart transplant, dies, available at: https://edition.cnn.com/2023/10/31/health/lawre

32 Wang Y, Lei T, Wei L, Du S, Girani L, Deng S. Xenotransplantation in China: present status. Xenotransplantation 2023;30:e12490.

nce-faucette-second-pig-heart-transplant-dies/index.html
5 CNN, Pig kidney successfully functions in human for over a month, available at: https://edition.cnn.com/2023/09/14/health/pig-kidney-transplant-long-term-scn/index.html
6 CNN, Pig kidney transplant patient discharged and recovering at home, available at: https://edition.cnn.com/2024/04/04/health/pig-kidney-transplant-patient-home/index.html
7 CNN, Woman is back on dialysis after doctors remove transplanted pig kidney, available at: https://edition.cnn.com/2024/05/31/health/pig-kidney-transplant-removal/index.html
8 CNN, Pig kidney transplant patient discharged and recovering at home, available at: https://edition.cnn.com/2025/02/07/health/pig-kidney-transplant-clinical-trials/index.html
9 U.S. Food and Drug Administration, Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans; Guidance for Industry, CBER, 13.12.2016; U.S. Department of Health and Human Services, PHS Guideline on Infectious Disease Issues in Xenotransplantation, 19.1.2001 (updated 23.6.2022) .
10 FDA, Roadmap to Reducing Animal Testing in Preclinical Safety Studies, available at: https://www.fda.gov/files/newsroom/published/roadmap_to_reducing_animal_testing_in_preclinical_safety_studies.pdf
11 Reuters, *US FDA to phase out animal testing in drug development*, available at: https://www.reuters.com/world/us/us-fda-phase-out-animal-testing-drug-development-2025-04-10/
12 Public Health Service PHS Guideline on Infectious Disease Issues in Xenotransplantation, 19.1.2001, updated 23.6.2022, available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/phs-guideline-infectious-disease-issues-xenotransplantation
13 Sorror MA, et al. Influence of comorbidities on outcome in 1102 patients with acute myeloid leukemia undergoing allogeneic hematopoietic cell transplantation. Bone Marrow Transplant 2024, 59: 115–123.
14 Denner J, Tönjes RR. Infection barriers to successful xenotransplantation focusing on porcine endogenous retroviruses. Clin Microbiol Rev 2012, 25: 318-343
15 Meije Y, Tönjes RR, Fishman JA. Retroviral restriction factors and infectious risk in xenotransplantation. Am J Transplant 2010, 10: 1240-1247.
16 Mehta SA, Saharia KK, Nellore A, Blumberg EA, Fishman JA. Infection and clinical xenotransplantation: Guidance from the Infectious Disease Community of Practice of the American Society of Transplantation. Am J Transplant 2023, 23(3): 309–315.
17 United Therapeutics Corporation. FDA clearance of Investigational New Drug application for UKidney™ clinical trial. 3.2.25, available at: https://ir.unither.com/press-releases/2025/02-03-2025-120011819
18 Healey N. World-first pig kidney trials mark turning point for xenotransplantation. Nature Medicine, 18.3.25. Available at: https://www.nature.com/articles/d41591-025-00020-0
19 We need this: Pig-to-human kidney transplants enter clinical trials. Healio, 27 June 2025. Available at: https://www.healio.com/news/nephrology/20250627/we-need-this-pigtohuman-kidney-transplants-enter-clinical-trials
20 Successful pig-to-human xenotransplant paves the way for clinical trials. Kidney News, 27.6.25. Available at: https://www.kidneynews.org/view/journals/kidney-news/17/4/article-p1_1.xml
21 Rollin B, Animal Rights and Human Morality, 1st ed, Prometheus Books, Buffalo, New York:
22 Bokota S. Defining human-animal chimeras and hybrids: A comparison of legal systems and natural sciences. Ethics & Bioethics (in Central Europe) 2021, 11(1–2): 101–114.
23 Cordis, EU funds project on chimera and hybrid research. 19.6.07.
24 Iltis AS, Koster G, Reeves E, Matthews KRW. Ethical, legal, regulatory, and policy issues concerning embryoids: a systematic review of the literature. Stem Cell Research & Therapy 2022, 13(1): 1–13.
25 Nicolas P, Etoc F, Brivanlou AH. The ethics of human-embryoids model: a call for consistency.

Journal of Molecular Medicine 2021, 99(4): 569–579.
26 European Parliament, Council of Europe, Use of human embryos and foetuses in scientific research, Recommendation 1100 (1989), available at: https://pace.coe.int/en/files/15134
27 Council of the European Union. Council adopts new rules on substances of human origin. 27.5.2024. Available at: https://www.consilium.europa.eu/en/press/press-releases/2024/05/27/council-adopts-new-rules-on-substances-of-human-origin/
28 OPTN Ethics Committee. Ethical Principles in the Allocation of Human Organs. IntechOpen, 2019: 3-10.
29 National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, 1979.
30 National Institute for Health and Care Excellence (NICE). Glossary: Utility. Available at: https://www.nice.org.uk/glossary?letter=u
31 Organ Procurement and Transplantation Network (OPTN). Ethical Principles in the Allocation of Human Organs. Available at: https://optn.transplant.hrsa.gov/professionals/by-topic/ethical-considerations/ethical-principles-in-the-allocation-of-human-organs/
32 Sykes M, d'Apice A, Sandrin M; IXA Ethics Committee. Position paper of the Ethics Committee of the International Xenotransplantation Association. *Xenotransplantation* 2003, 10: 194-203.
33 Menell J, Allison M, Wolf L. Regulatory aspects of clinical xenotransplantation. Xenotransplantation 2015, 22:205-13.
34 World Health Organization, Guidance on Xenogeneic Infection/Disease Surveillance and Response: a strategy for international cooperation and coordination, WHO, Geneva, 2001 .
35 WHO. Guidance on Xenogeneic Infection/Disease Surveillance and Response: A Strategy for International Cooperation and Coordination.
36 World Health Organization, First WHO global consultation on regulatory requirements for xenotransplantation clinical trials, Changsha, China, 19–21 November?2008: the Changsha Communiqué, WHO, Geneva, 200.
37 World Health Organization, Second WHO Global Consultation on Regulatory Requirements for Xenotransplantation Clinical Trials, Geneva, 2011.
38 World Health Organization, Third WHO Global Consultation on Regulatory Requirements for Xenotransplantation Clinical Trials, Geneva, 2018.
39 Hawthorne WJ. Ethical and legislative advances in xenotransplantation for clinical translation: focusing on cardiac, kidney and islet cell xenotransplantation, Front Immunol 2024.
40 European Medicines Agency. Advanced Therapy Medicinal Products: Overview. EMA, London, 2025.
41 Swiss Confederation. Federal Act on the Transplantation of Organs, Tissues and Cells (Transplantation Act). Fedlex, 810.21, 1.7.2007;
42 Wang Y, Lei T, Wei L, Du S, Girani L, Deng S. Xenotransplantation in China: present status. Xenotransplantation 2023;30:e12490.

Ανασκόπηση

Uterine Transplants – Considerations of Legal Frameworks, Access for Transgender Women, and Ethical Considerations

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Abstract

Uterine transplantations (UTx) are rapidly gaining popularity as an artificial reproductive technique (ART). Uterine transplantations (UTx) refer to a surgical procedure whereby a healthy uterus is transplanted from one person to another. Up to date, UTx procedures have been performed on cisgender women who struggle with some sort of infertility, whether that be Absolute Uterine Factor Infertility or Mayer-Rokitansky-Küster-Hauser (MRKH) syndrome, a disorder where someone is born without a uterus. Though this procedure is not currently offered as routine treatment in any country worldwide, it is essential to determine the key ethical and legal debates surrounding the procedure in order to determine whether current organ transplantation laws are adequate for this procedure, or if new legislation is necessary in order to capture the complex nature of the procedure. UTX not only involves the routine complexities of any organ donations, such as kidney donations, but it also creates a unique level of added harm for both the donor and the recipient. Currently, no country has suggested to bring forward specific legislation regarding this procedure. However, I will argue that it is essential to view this ART as a different level of organ donation, thus requiring an individual set of legislation. UTx specific legislation will aid to combat inequalities and prevent coercion at an international level. This article will establish three main considerations regarding this procedure. Firstly, I will ask whether a new legal framework is required in order to deal with the issue of uterine transplants, or will it be sufficient to apply current rules regarding organ transplantations? I will analyse laws regarding access to UTx in the following countries: Sweden, Lebanon, the United Kingdom, and the United States., I will seek to establish the medical and ethical considerations regarding access to uterus transplants for transgender women, how it would be physiologically possible, and the importance of allowing access to uterus transplants for this subgroup of women. I will seek to point out a myriad of ethical issues that arise from the procedure, such as deceased donations, fair distribution, whether the procedure should be made available for cisgender and transgender men, the principle of harm and whether this level of harm to the donor and to the recipient could be ethically acceptable, and finally, the right to procreate and where UTx lies within this right. Ultimately, I will seek to establish that a new and innovative set of legislation should be implemented in order to encapsulate the complex nature of UTx.

Keywords: Uterine transplantations, organ donation, organ transplantation laws, transgender/cisgender persons, right to procreate.

Μεταμοσχεύσεις μήτρας – Σκέψεις σχετικά με το νομικό πλαίσιο, την πρόσβαση των τρανσέξουαλ γυναικών και τα ηθικά ζητήματα

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Περίληψη

Οι μεταμοσχεύσεις μήτρας (UTx) κερδίζουν γρήγορα δημοτικότητα ως μέθοδος τεχνητής αναπαραγωγής. Αφορούν μια χειρουργική επέμβαση κατά την οποία μια υγιής μήτρα μεταμοσχεύεται από ένα άτομο σε ένα άλλο. Μέχρι σήμερα, οι διαδικασίες UTx έχουν πραγματοποιηθεί σε γυναίκες με ταυτότητα φύλου (cisgender) που αντιμετωπίζουν κάποιο είδος υπογονιμότητας. Αν και αυτή η διαδικασία δεν προσφέρεται επί του παρόντος ως συνήθης θεραπεία σε καμία χώρα παγκοσμίως, είναι απαραίτητο να προσδιοριστούν τα βασικά ηθικά και νομικά ζητήματα, προκειμένου να καθοριστεί εάν οι ισχύοντες νόμοι για τη μεταμόσχευση οργάνων είναι κατάλληλοι ή εάν απαιτείται νέα νομοθεσία. Θα υποστηρίξω ότι η μέθοδος αυτή έχει ιδιαίτερη πολυπλοκότητα, που απαιτεί ένα ξεχωριστό σύνολο νομοθετικών διατάξεων. Η ειδική νομοθεσία για την UTx θα συμβάλει στην καταπολέμηση των ανισοτήτων και στην πρόληψη του εξαναγκασμού σε διεθνές επίπεδο.

Λέξεις κλειδιά: Μεταμοσχεύσεις μήτρας, δωρεά οργάνων, νόμοι περί μεταμόσχευσης οργάνων, διεμφυλικά/ταυτοφιλικά άτομα, δικαίωμα στην αναπαραγωγή.

Introduction

Uterine transplantation surgery (UTx) has been performed worldwide on approximately 100 women. This innovative procedure has the potential for infertile women to experience biological motherhood, which is the main difference between UTx and other artificial reproductive techniques (ARTs). This incredible achievement for the world of ARTs, however, is overshadowed by a myriad of ethical considerations and debates. This article aims to cover the key ethical debates surrounding UTx and will aim to establish that there is a need for UTx specific legislation in order to cover the level of harm that this procedure entails for both the donor and the recipient of the uterus. It is essential that UTx specific legislations are passed before the procedure is made routine-treatment in any country, which is currently not the position.

Legal Considerations

In order to establish whether a new set of legislation is required and in order to address the complexities of UTx, it is essential to examine laws surrounding organ donation, specifically of uteri globally, in order to compare and contrast the most and least efficient legal approaches to this procedure. In order to do this, I will examine the law regarding UTx in the following countries: Sweden, Lebanon, the United Kingdom, and the United States. These locations were chosen as examples due to the accessibility of research coming out of these countries. By analysing the legal frameworks relating to UTx in a variety of countries, I will aim to observe effective and non-effective legal approaches pertaining to this procedure, ultimately considering whether a specific legal standpoint is needed in cases relating to uterine transplantations.

Sweden is one of the most advanced countries regarding legislation pertaining to UTx donations. Organ donation in Sweden is governed by the Swedish Transplantation Act.[1] The Act creates special conditions for donations if the organ, like the uterus, does not regenerate.[2] 'To take nonregenerative material, the donor's consent must be given in writing (section 6) and the donor must be a family member or have a close relationship to the recipient, unless special circumstances apply. A close relationship is considered to include generally only spouses, registered partners or cohabitants. Only people who, due to their relationship with the patient, have a very strong interest in helping the patient should be considered as donors.'[3] Whilst this approach ensures that no coercion of donation will take place in terms of financial needs, it could be argued that pressure could still be placed on people close to infertile women. For example, if a sister has had three children and is no longer planning on childbearing in the future, and another sister is not able to conceive a pregnancy or see a pregnancy through full term, societal and familiar pressure could be placed on the sister to donate her uterus to her sister. This is a key flaw of the close relationship donation legislative model for the donation of uteri. Bergius et al argue that this legislative approach is restrictive due to the fact that living uteri donations are limited to people with a close relationship with the recipient. They state that 'the possibility of using living donors for UTx is

[1] Swedish Transplantation Act 1995:831, section 1
[2] M. Bergius, T. Mattsson, L.Wahlberg, Uterine Transplantations in Sweden, International Legal and Ethical Perspectives on Uterus Transplantation, Edward Elgar Publishing Limited, London, 2024, p 230.
[3] *Ibidem.*

thus relatively constrained.'[4] Sweden's consideration for the non-regenerative nature of the uterus is a net positive. However, this law is not sufficiently thorough in terms of addressing the level of harm that the procedure creates for both the donor and the recipient. Due to this, even though Sweden's laws are the most thorough regarding UTx and uteri donations, it would be preferrable to have UTx-specific legislation.

According to Hazae Haidar, Tala Khansa and Thalia Arawi, 'in 2018, the first UTx was conducted within a clinical context in Lebanon. The recipient was a 24-year-old woman with Mayer-Rokitansky-Küster-Hauser (MRKH) syndrome, congenital absence of the uterus, and the living donor was her 50-year-old multiparous mother.'[5] This medical trial resulted in 'the first successful live birth in Lebanon and the Middle East, North Africa, and Turkey (MENAT) region' in January 2020.[6] UTx is still 'considered as having clinical trial status', and as such 'there are currently no specific legal guidelines in Lebanon for the regulation of UTx.'[7] Haidar et al argue that 'it is no coincidence that UTx trials started to be performed in MENAT countries, where this reproductive procedure might constitute a way to achieve motherhood for those women suffering from AUFI (absolute uterine factor infertility) and for whom other alternatives such as adoption and surrogacy are legally prohibited.'[8] Lebanon also faces cultural challenges that may be address through the development of UTx. As 'an Arab country, Lebanon is a pronatalist society where childless marriages are usually frowned upon… Consequently, many women feel indirectly coerced to do whatever it takes to conceive and give birth to their "genetic" child.'[9] Haidar et al argue that 'the overview of the Lebanese social fabric, including religious authorities' positions on adoption and surrogacy as options to address infertility, clarifies why UTx is attractive in the Lebanese setting, especially for Muslim communities, where surrogacy is highly controversial and adoption is unacceptable from a religious viewpoint.'[10] "According to Islam, children are considered a blessed gift of Allah: 'Wealth and children are an ornament of life of the world' (Qura'n 3:6, 4:1, 6:143-144, 8:75, 13:8). Therefore, for Middle Eastern Muslims, procreation is highly desirable as parenthood is culturally and socially prized."[11] Islamic law generally allows organ donation under certain conditions, such as obtaining authorisation from the donor, ensuring minimal harm to the donor and respecting specific prohibitions. This might be a hurdle to overcome in the path of creating UTx specific legislation, as it could be argued that uterus donors can go through a great deal of harm, namely, infertility. Furthermore, 'in the case of reproductive organs that carry genetic material, such as testes and ovaries, transplantation is not allowed as the genetic material belongs to the donor".[12] This principle highlights Islamic teachings regarding "the importance of preserving genetic lineage and clear parentage". [13] This makes UTx generally permissible, as the uterus does not allow

[4] *Ibidem.*
[5] H. Haidar, T. Khansa and T. Arawi, Uterine transplantation in Lebanon: social, ethical, and legal considerations, Edward Elgar Publishing Limited, London, 2024, p 256.
[6] *Ibidem.*
[7] *Idem* p 256 and p 257.
[8] *Idem 257.*
[9] *Ibidem.*
[10] *Idem, p 263.*
[11] *Ibidem.*
[12] *Idem, p 264.*
[13] *Ibidem.*

for the transmission of genetic material. [14] Haidar et al highlight this statement, warning that 'when UTx becomes clinically available, there will be numerous regulatory hurdles to overcome in the Lebanese setting, beginning with obtaining approval from various religious authorities.'[15] Lebanon offers a unique perspective on the issue of UTx. Given the focus of gestational motherhood that is highly encouraged by religious figures and authorities, a specific set of UTx legislation may be the best way forward in order to ensure that all women in Lebanon whether Muslim or Christian could have access to this procedure. Lebanon is another clear example of the need for UTx specific legislation, as other forms of ARTs are explicitly prohibited by religious and governmental organisations.

The United States' current position on the limitation of ARTs, abortion, and other means of women's health offers a unique perspective regarding the issue of UTx. According to Valarie Blake and Seema Mohapatra, in the United States 'UTx, which includes invitro fertilization, encounters a small body of laws governing assisted reproduction and, more importantly, a historically divisive battle over reproductive freedoms which is currently at fever pitch after the recent demise of the federal right to abortion.'[16] They highlight that 'there is a great concern that reproductive practices such as IVF that are used in conjunction with UTx could be swept up in the overregulation of pregnant people's bodies in the US, especially as the US is undergoing a period of rights retraction.'[17] Due to this, they argue that 'as UTx becomes more available, it may be necessary to pass UTx-specific regulations and laws to protect the parties involved.'[18] However, they warn that 'this seems increasingly unlikely and fraught given the shifting landscape of reproductive rights and freedoms in the US.'[19] Given the current culture wars in the United States, and the vastly different views on access to ARTs, it will be interesting to see how these varying decisions will reflect in different states throughout the country. In February 20204, 'The Alabama Supreme Court issued a ruling… declaring that embryos created through in vitro fertilization (IVF) should be considered children.'[20] Judicial decisions such as these at the state level could mean that there could be great discrepancies in the field of reproductive technologies. This may, in turn, lead to a possible form of medical tourism within the country, as people could potentially travel to other states to access their desired treatments. This principle of internal medical tourism is already being observed through travel through state lines in order to receive adequate healthcare regarding fertility. The suggestion for legislation specific to UTx that this article offers could seem somewhat problematic in the United States and in other federal jurisdictions. Federal jurisdiction could create a potential challenge to access and equity in regards to this procedure, meaning that some women may have access to certain ARTs, such as UTx, and others within the same country will be unable to access even simpler access to women's healthcare, such as abortion and contraceptive care. Due to this, it

[14] *Ibidem.*
[15] *Idem*, p 273.
[16] V. Blake and S. Mohapatra, Regulating uterus transplantation: the United States, Edward Elgar Publishing Limited, London, 2024, p 241.
[17] *Idem*, p 254.
[18] *Ibidem.*
[19] *Ibidem.*
[20] A. Rosen, The Alabama Supreme Court's Ruling on Frozen Embryos, John Hopkins University, Bloomberg School of Public Health, 2024 <https://publichealth.jhu.edu/2024/the-alabama-supreme-courts-ruling-on-frozen-embryos>

could be argued that the suggestion to create UTx specific care, even though efficient for most jurisdictions, may create a certain level of inequality in federal jurisdictions.

Transgender Women's Right to Uterus Transplantations

In order to cover transgender women's right to UTx, I will comment on United Kingdom legislation pertaining equality and access to healthcare for transgender women. In England and Wales, The Human Tissue Act 2004 'regulates the donation, removal and transplantation of human organs and tissues, and established the Human Tissue Authority.'[21] [22] According to Natasha Hammond-Browning, 'the legislative challenge is that the donation and transplantation of uteri was unheard of when the Human Tissue Bill was drafted and debated, and UTx has not been at the forefront of law makers' minds with subsequent legislative progress in this area, so that the regulation of UTx has to fit within existing legislative regimes that were designed and implemented without UTx in mind.'[23] Hammond-Browning highlights the issues that UTx would bring about regarding legal parentage in the United Kingdom. According to Natasha Hammond-Browning, 'worldwide, current UTx recipients are cis-gender women with Absolute Uterine Factor Infertility, and the relevant legal parentage provisions are applied to this group.'[24] However, 'UTx offers the possibility of gestational parenthood for transgender women, transgender men and cisgender men, and the current parentage provisions are also applied to these potential recipients, highlighting the difficulties with the current provisions.'[25] Hammond-Browning argued that 'UTx may be desired by transgender women for reproductive means, or alternatively as a method to fulfil their gender realignment. Gender reassignment is a protected characteristic; transgender people are given explicit protection from indirect and direct discrimination under the Equality Act 2010.'[26] [27] Therefore, in the United Kingdom, it would be 'legally impermissible to refuse to perform UTx in transgender women solely because of their gender identity.'[28] Hammond-Browning argues that 'although there are not yet any clinical trials performing UTx in transgender women, and notwithstanding the medical considerations it involves, the legal parentage of transgender women who utilise UTx to gestate and birth a child must be examined before the procedure is performed.'[29] UK courts were recently faced with the question of legal parentage regarding a transgender parent in the case of *R (on the application of TT) v The Registrar General for England and Wales*.[30] This case involved 'a transgender man who had received a gender recognition certificate and subsequently un-

[21] N. Hammond-Browning, Regulating uterus transplantation: the United Kingdom, Edward Elgar Publishing Limited, London, 2024, p 276.
[22] The Human Tissue Act 2004.
[23] N. Hammond-Browning, *op. cit.*, p 276.
[24] *Idem*, p 281.
[25] *Ibidem.*
[26] *Idem*, p 285.
[27] The Equality Act 2010.
[28] BP. Jones, NJ. Williams, S. Saso, M-Y. Thum, I. Quiroga, J. Yazbek, S. Wilkinson, S. Ghaem-Maghami, P. Thomas, JR. Smith, Uterine Transplantation in Transgender Women, BJOG: An International Journal of Obstetrics & Gynaecology, Volume 126, Issue 2, 2019, p 152.
[29] N. Hammond-Browning, *op. cit.*, p 285.
[30] *R (on the application of TT) v The Registrar General for England and Wales* [2019] EWHC 2384 (Fam).

derwent intrauterine insemination (IUI) resulting in pregnancy and birth.'[31] [32] The court held that even though a transgender man would be giving birth, 'in common law, the person who carries a pregnancy and gives birth to a child is that child's mother' due to the legal principle of *mater semper certa est* (the mother is always certain), which was later ratified in the Human Fertilisation and Embryology Act 1990.[33] [34] [35]Although this principle is restricting for transgender men who give birth, it would mean that any transgender woman who gives birth through procedures such as UTx would be the legal mother of any child they conceive and birth, creating a unique legal standpoint that would reshape the preconceived notion of motherhood, expanding the legal understanding of the term "mother".

Natasha Hammond-Browning argues that 'whilst UTx for transgender women and men may become medically possible… there is uncertainty around the legality of transferring IVF embryos to bodies that are anatomically male.'[36] The Human Fertilisation and Embryology Act 1990 states that the transfer of embryos is permitted 'for the purpose of assisting women to carry children.'[37] Hammond-Browning argues that 'there is an incongruity between society's increasing acceptance of transgender (and others) people's right to present and be accepted in the gender they identify with, and the expectation to apply for legal recognition of a gender other than the one assigned at birth.'[38] The Gender Recognition Act 2004 states that 'a person of either gender who is aged at least 18 may make an application for a gender recognition certificate', therefore there is no legal requirement to 'seek recognition of one's gender where it is different to that assigned at birth.'[39] [40] Hammond-Browning argues that 'it must be considered if it is legally permissible to transfer embryos to someone other than a cisgender woman or a transgender man without a gender recognition certificate (as they would legally remain a woman).'[41]

According to a recent report by the George Washington University School of Medicine and Health Sciences in Washington DC, 'currently, uterine transplantation has only been conducted in cisgender women, and there has been little progress on its successful application to the transgender population.'[42] Furthermore, they state that 'uterine transplantation has the potential to transform the way gender identity is discussed and understood in regards to transgender MtF (Male to Female) individuals.'[43] They argue that 'the female identity has been chiefly constructed around the idea of reproduction and childbirth' and that 'extending the capability of having biological children through suc-

[31] N. Hammond-Browning, *op. cit.*, p 285.
[32] *R (on the application of TT) v The Registrar General for England and Wales* [2019] EWHC 2384 (Fam).
[33] N. Hammond-Browning, *op. cit.*, p 283 and p 285.
[34] *R (on the application of TT) v The Registrar General for England and Wales* [2019] EWHC 2384 (Fam).
[35] Human Fertilisation and Embryology Act 1990.
[36] N. Hammond-Browning, *op. cit.*, p 287.
[37] Human Fertilisation and Embryology Act 1990, section 2.
[38] N. Hammond-Browning, *op. cit.*, p 287.
[39] *Ibidem.*
[40] Gender Recognition Act 2004 section 1(1).
[41] N. Hammond-Browning, *op. cit.*, p 288.
[42] A. Shetty, Y. Dong, J. Goldman, M. Akiska, B. Ranganath, Uterine Transplantation in Transgender Individuals as Gender Affirmation Surgery, George Washington University School of Medicine and Health Sciences, Washington DC, 2023, p 1.
[43] *Ibidem.*

cessful uterine transplantation and live birth blurs the distinction between transgender women and individuals born as biological females.'[44] They conclude their report by claiming that 'uterine transplantation has the incredible capacity to not only redefine gender identity as a social concept, but also to expand the scope of medical care in women's reproductive health.'[45]

In the case of transgender women's access to UTx in the United Kingdom, it would seem that UTx-specific legislation would be the best way forward in order to ensure equitable access to this procedure for all women. Legislation pertaining to ARTs is highly outdated and does not reflect the needs of today's women, given the growth of technological advances in reproductive technologies. Societal advances are also misrepresented by the current set of laws that govern access to reproductive technologies. Societal acceptance of transgender women has grown significantly, and equal access to legal protections would have been unlikely in the years where these sets of legislation were passed. Due to the fact that lawmakers in the United Kingdom seem unwilling to overhaul these pieces of legislation, UTx-specific legislation would be a good temporary solution in order to ensure gestational motherhood for transgender women and therefore, equal access to fertility treatment for all women in the United Kingdom.

Ethical Considerations

In order to establish the terms of UTx-specific legislation proposed in this article, it is essential to highlight ethical considerations concerning the procedure.

One of the key ethical considerations regarding uterine transplantations is deceased donations. Bethany Bruno and Kavita Shah Arora argue that, in general, 'deceased organ donation for lifesaving organs is morally based in the principles of rescue ethics' as we have 'a moral responsibility… to save endangered human life whenever possible.'[46] 'Postmortem organ removal involves no physical risks, costs, or inconvenience to the donor, and the ability to save lives justifies desecration of the deceased's body.'[47] However, Bruno and Arora argue that 'while the ability to save lives justifies desecration of the deceased's body, it is not immediately clear that the ability to improve quality of life does the same.'[48] 'Nonetheless, science and society at large have permitted donation of other quality-of-life donations, including vascular composite allografts (VCAs) for face and arm transplantation' from deceased donors, thus, 'it seems that society has broadened the justification for deceased organ donation from the rule of rescue to a more general appeal to beneficence.'[49] Nonetheless, it could be argued that 'unlike face and arm transplants, uterus transplants are ephemeral in nature', as the uterus is removed after childbirth.[50] It is therefore essential to determine whether being presented with the opportunity to experience gestation would be a sufficient reason to be able to obtain uteri from deceased donors.[51] The procurement of the uteri also poses a key question. According to Bruno and Aro-

[44] *Ibidem.*
[45] *Ibidem.*
[46] B. Bruno, K. Shah Arora, Uterus Transplantation: The Ethics of Using Deceased Versus Living Donors, American Journal of Bioethics, Volume 18, Issue 7, 2018, p 7.
[47] Ibidem.
[48] Ibidem.
[49] *Ibidem.*
[50] *Ibidem.*
[51] *Ibidem.*

ra, 'procurement of the uterus as a nonvital organ should occur after procurement of vital organs.'[52] Uterus removals typically last between 18-90 minutes.[53] Due to the timeframe within which organ removals must be carried out, procurement of non-vital organs, including the uterus, would be improbable in most cases of deceased donation.[54] The likelihood of uterus removals from deceased donors must be established in any UTx-specific legislation which may be brought forward. It is essential to highlight the fact that deceased procurement is unlikely and other vital organs must be prioritised. In Sweden, deceased donations were historically constrained. This principle is highlighted through current Swedish law. 'Until 1 July 2022, donation where the donor's will was unknown was not permitted if the donor's next of kin objected to the intervention.'[55] However, 'a recent change in legislation has abolished the family veto.'[56] Swedish law now allows organ donations not only following brain death, but also following circulatory death.[57] This legal change also allows 'organ preserving treatments on not yet deceased donors if there is no indication that this would be against the donor's will.'[58] 'In its 2016 commentary on UTx, the Swedish National Council on Medical Ethics (Smer) stated that due to the significant uncertainties associated with the risks to which UTx exposes the mother and child, the treatment could not yet be offered within regular health care.'[59] [60] It is crucial, however, to keep in mind that this opinion was given in 2016. Bergius et al argue that 'considering the rapid development of medical knowledge and techniques in this domain, it is not unlikely that UTx will be considered sufficiently safe and effective in the near future.'[61]

Fair distribution and allocation of uteri is another one key ethical debates surrounding the procedure of uterine transplantations. Ryan Tonkens argues that a "womb lottery" would be the most fair and efficient way to ensure access to those people who want the procedure.[62] He argues that 'in the wider context of the allocation of scarce medical resources, noted benefits of a lottery system include its simplicity, that it is resistant to corruption, that it is egalitarian in the sense that each person in the pool of eligible recipients is given equal opportunity to "win the lottery", that it prevents small differences across individual candidates from generating drastically different outcomes, that lotteries can be quick in terms of decision making, and that they do not require a great depth of information about the candidates.'[63] Tonkens argues that in the case of UTx, there is no need to apply 'standard

[52] *Ibidem.*
[53] Lavoué, V., C. Vigneau, S. Duros, K. Boudjema, J. Levêque, P. Piver, Y. Aubard, T. Gauthier., Which donors for uterus transplants: Brain-dead donor or living donor? A systematic review, Transplantation 101(2), 2017, p 271.
[54] B. Bruno, K. Shah Arora, *op. cit*., p 7.
[55] M. Bergius, T. Mattsson, L. Wahlberg, *op. cit*., p 230.
[56] *Ibidem.*
[57] *Ibidem.*
[58] *Ibidem.*
[59] *Idem*, p 232.
[60] Swedish National Council on Medical Ethics, (SMER) S1985:A/2016/00675 2016-09-26.
[61] M. Bergius, T. Mattsson, L. Wahlberg, *op. cit*., p 233.
[62] R. Tonkens, Gatekeeping uterus transplants: a proposal for eligibility criteria and the fair allocation of wombs, International Legal and Ethical Perspectives on Uterus Transplantation, Edward Elgar Publishing Limited, London, 2024, p 140.
[63] *Idem*, p 141.

principles of distributive justice in healthcare', as 'UTx is not life-saving' and 'the potential recipients have the same goal and similar interests at stake, and people with AUFI are generally infertile to the same degree.'[64] Due to this, he also argues that it would be 'unfair to give priority to people just because they have been on the waiting list for longer than others.'[65] Thus, he concludes that 'random allocation is the fairest option, such as distribution of the available uteri to eligible recipients via a womb lottery.'[66] Michelle J. Bayefsky and Benjamin E. Berkman present a myriad of elements that must be considered when allocating uteri. These are: motivation to seek treatment, the age of the recipient, the child rearing capacity of the woman, and the amount of infertility treatment required.[67] Inequality in access to available uteri is a key consideration which must be addressed in UTx-specific legislation. According to Mustafa Akan, 'recognising the effects of health inequalities related to transplantation is important for underserved populations.'[68] It is therefore essential to determine potential inequities that could be brought forward when considering the implementation of UTx-specific legislation. The lottery system proposed by Ryan Tonkens could prove to be successful when it comes to this perspective.

Access to UTx for cisgender men is another key ethical consideration regarding this procedure. In a study conducted by Jabulile Mary-Jane Jace Mavuso, 'six cisgender men were interviewed about their desires to be pregnant and/or a gestational parent.'[69] The results of the study indicated that 'all but one said that they would not use a womb transplant to enable pregnancy.'[70] Due to these results, Jace Mavuso argues that normative sex/gender discourses would allege 'that most cis men would not take up the opportunity to become pregnant, and/or that womb transplant technology should not include cis men as recipients.'[71] However, Jace Mavuso argues against this, stating that the men's responses 'reveal the ways in which discourses frame understandings of ARTs, pregnancy, reproduction, parenthood, and sex/gender, and how these, along with the normative social practices described by participants come to bear on the reproductive desires and decision-making of the cis men in the study who would not utilise womb transplant technology to become pregnant.'[72] She goes on to argue that she does not 'believe the findings to be exhaustive of whether cis men desire to be pregnant, nor whether cis men would use womb transplant technology to enable their pregnancies' however, she claims that she believes 'that there are many more men who want to be pregnant, and who would be recipients of womb transplantation in order to do so, than is reflected in this study.'[73] She

[64] *Idem*, p 142.
[65] *Ibidem.*
[66] *Ibidem.*
[67] MJ. Bayefsky, E. Berkman, The Ethics of Allocating Uterine Transplants, Cambridge Quarterly of Healthcare Ethics, Cambridge University Press, Cambridge, 2016, p 353-361.
[68] M. Akan, Transplant health inequities research from an operations perspective, Health Sciences Review 11, 100176, Tepper School of Business, Carnegie Mellon University, USA, 2024, p 1.
[69] JMJJ. Mavuso, Repronormativity in cisgender men's reasons why they would not use womb transplant technology to become pregnant, Sociology Compass, Volume 17, Issue 2, e13054, Sociology Department, University of Pretoria, Lynwood, South Africa, 2022, p 11.
[70] *Ibidem.*
[71] *Ibidem.*
[72] *Ibidem.*
[73] *Idem*, p 13.

states that 'various groups of people are positioned as "illegitimate", and "undesirable" gestational reproducers, and therefore ultimately as non-gestational reproducers, if reproducers at all.'[74] She states that 'in particular, men (trans and cis), are assumed to have no ('real') desire nor real requirement of this form of reproductive assistance because they are men, an illogic that is underpinned by and reinforces the construction of masculinity as non-uterine and non-gestational.'[75] Jace Mavuso denounces the current medico-socio-cultural environment that would, in theory prevent men (trans or cisgender) to become pregnant through UTx if they would so choose to, arguing that 'the findings of this study require us to resist such "comfortable" and beguiling explanations, to push beyond the confines of repronormativity, including patriarchal logistics' claiming that 'doing so may put us in a better position to reckon with the fullness of repronormativity, including how it may shape cis men's desires to not receive a womb transplant (and any other technologies).'[76] As previously stated regarding access to UTx for transgender women, many provisions worldwide regarding ARTs are specifically created with access for women and women alone. UTx offers a unique way to gestate which could be physiologically available to those who identify as male. It is therefore essential to determine whether this procedure should be made readily available to those who desire to carry a child regardless of gender before implementing UTx-specific legislation. Access to all seems ethically permissible as long as technological advancements allow for this procedure to occur in people assigned male at birth (AMAB).

The principle of harm is another main ethical consideration regarding uterine transplantations. According to Gulzaar Barn, 'UTx seems to demand a peculiar harm' as 'live uterus donors divest themselves of an organ in its entirety and lose that organ's attendant functioning.'[77] This makes this procedure stand out from others usually tested through clinical trials, as 'no clinical trial using healthy volunteers exposes participants to drugs that would permanently stop the functioning of one of their organs, and no other living donor surgery removes a body part that cannot be replaced or regenerated.'[78] Due to this, 'UTx should primarily be viewed as a major transplant surgery rather than merely an assisted reproductive service, to correctly capture the novel harm at stake.'[79] Due to this, 'UTx raises novel concerns surrounding living uterine donation and harm that arguments for rights-based access must reckon with'.[80] This 'may problematise the function of consent as a normative transformer and undermine a rights-based justification for access.'[81] Barn argues that access to UTx could be morally acceptable through a negative right, stating that 'in the case of UTx, it seems plausible that a negative right to UTx might conflict with a negative right to be free from harm.'[82] However, the principle of harm may be balanced out and reduced by quality of life arguments. According to Roman Chmel et al, 'non-life-saving

[74] *Ibidem.*
[75] *Ibidem.*
[76] *Ibidem.*
[77] G. Barn, A right to gestate? Uterus transplants and the language of rights, International Legal and Ethical Perspectives on Uterus Transplantation, Edward Elgar Publishing Limited, London, 2024, p 72.
[78] *Ibidem.*
[79] *Ibidem.*
[80] *Idem*, p 73.
[81] *Ibidem.*
[82] *Idem*, p 72.

transplantations have been ethically justified based on the quality-of-life improvement.'[83] However, they go on to warn that UTx may differ from other non-life-saving transplantations such as facial or hand transplants due to 'the need of lifetime immunosuppressive agents.'[84] Furthermore, UTx recipients 'are exposed to several risks in the pre- and posttransplant periods' such as 'ovarian hyperstimulation syndrome', 'ovarian bleeding' and 'hemoperitoneum.'[85] The level of harm for both donors and recipients must be considered prior to enacting UTx-specific legislation.

The right to procreate, or more specifically for the purposes of this article, to gestate is a main ethical point surrounding the procedure of uterine transplantations. According to Gulzaar Barn, 'the question as to whether there is a right to procreate, under which a right to UTx may fall, can be situated in a broader debate that examines the coherence of moral and natural rights, as separable from legal rights.'[86] Barn analyses whether access to UTx could be covered by Article 8 of the ECHR.[87] He argues that 'to suggest that denying access to UTx would similarly infringe Article 8 seems implausible, as even in the absence of UTx, there exist other means to a family life' such as adoption.[88] A similar point is highlighted by Mianna Lotz, who states that 'adoption is not an appropriate solution for everyone who desires to be a parent, nor for every child in out-of-home care.'[89] Furthermore, due to the level of harm for both the donor and the donee of UTx, Barn argues that UTx is 'crucially different from other assisted reproductive technologies and may impose limits on an interpretation of the right to a family, gestation or genetic reproduction that relies upon this procedure.'[90] However, he points to the fact that 'for some people there might be no other ways outside of UTx to have a genetic family', such as people who are unable to access other forms of ART or adoption.[91] He argues that 'a right to have children might be distinguished from a right to be given access to the means necessary to have children.'[92] He claims that 'a positive right to UTx that involved forcible redistribution of reproductive materials or coerced access to reproductive means would of course be straightforwardly in conflict with other people's negative rights, and therefore unsustainable.'[93] However, 'a positive right could involve a weaker duty upon the state to fund research and facilitate the consensual donation of uteri.'[94] It is essential to determine whether the right to gestate could be seen as a right which falls under the ECHR, and if so, where UTx falls into this particular right. Whilst UTx offers a clear way to create a gestational and genetic family, it could be argued that this right does not give

[83] R. Chmel, Z. Pastor, J. Matecha, L. Janousek, M. Novackova, J. Fronek, Uterine transplantation in an era of successful childbirths from living and deceased donor uteri: Current challenges, Biomedical Papers, Medical Faculty University of Palacky Olomouc, Czech Republic, 2020, p 116.
[84] *Ibidem.*
[85] *Ibidem.*
[86] G. Barn, *op. cit*., p 61.
[87] *Idem*, p 63.
[88] *Ibidem.*
[89] M. Lotz, Uterus transplantation and adoption in the empirical and normative context: the question of alternative parenthood modalities, International Legal and Ethical Perspectives on Uterus Transplantation, Edward Elgar Publishing Limited, London, 2024, p 54.
[90] G. Barn, *op. cit.*, p 64.
[91] *Idem*, p 70.
[92] *Idem*, p 71.
[93] *Ibidem.*
[94] *Ibidem.*

automatic access to the limited supply of uteri available worldwide and it does not answer the question of who should have access to uteri.

Conclusion

In conclusion, it is essential to create legislation pertaining specifically to uterine transplantations. Given the growth of UTx operations and subsequent births worldwide, it is essential to create legislation which ensures equality and accessibility for all. Sweden's current legislation regarding the procedure seems to be the most effective to date, as it takes the non-regenerative nature of organs into account. However, the level of harm that the procedure entails is not efficiently covered. UTx in Lebanon offer a unique approach to this procedure, as it is a country with limited access to ARTs and its population sees gestational parenthood as an integral part of family life. It is a clear example of why UTx-specific legislation is required, and should not be lumped together alongside other ARTs, as most other procedures would be impermissible in such societies. The United States' current stance on abortion the limitation to women's access to healthcare also highlights the need for UTx-specific healthcare. In-vitro fertilisation, which is an essential component of UTx, is being challenged in the country, which would, in turn, limit access to UTx. However, the current culture wars taking place in different states across the country may lead to internal medical tourism, with some women crossing state lines in order to access ARTs. This could be seen as a negative of the suggestion to create UTx-specific legislation, as it may create inequalities in federal jurisdictions. It is also essential to establish equitable access to UTx for transgender women, which would in turn mean creating either UTx-specific legislation, or a complete overhaul of legislation regarding ARTs.

Key ethical considerations, such as deceased donations, fair distribution, access to cisgender men, the principle of harm, and the right to gestate must also be considered before the implementation of UTx-specific legislation. The consideration of these debates will ensure equitable access for all who wish to access this procedure.

Acknowledgments

I thank Dr Takis Vidalis for providing valuable feedback on previous versions of a report covering this topic which was, in turn, converted to this article.

Bibliography

1. Swedish Transplantation Act 1995:831
2. M. Bergius, T. Mattsson, L.Wahlberg, Uterine Transplantations in Sweden, International Legal and Ethical Perspectives on Uterus Transplantation, Edward Elgar Publishing Limited, London, 2024: 230.
3. H. Haidar, T. Khansa and T. Arawi, Uterine transplantation in Lebanon: social, ethical, and legal considerations, Edward Elgar Publishing Limited, London, 2024: 256-273.
4. V. Blake and S. Mohapatra, Regulating uterus transplantation: the United States, Edward Elgar Publishing Limited, London, 2024: 241-254.
5. A. Rosen, The Alabama Supreme Court's Ruling on Frozen Embryos, John Hopkins University, Bloomberg School of Public Health, 2024 <https://publichealth.jhu.edu/2024/the-alabama-supreme-courts-ruling-on-frozen-embryos>
6. N. Hammond-Browning, Regulating uterus transplantation: the United Kingdom, Edward Elgar Publishing Limited, London, 2024: 276-288.
7. The Human Tissue Act 2004.
8. The Equality Act 2010.
9. BP. Jones, NJ. Williams, S. Saso, M-Y. Thum, I. Quiroga, J. Yazbek, S. Wilkinson, S. Ghaem-Maghami, P. Thomas, JR. Smith, Uterine Transplantation in Transgender Women, BJOG: An International Journal of Obstetrics & Gynaecology, Volume 126, Issue 2, 2019: 152.
10. R (on the application of TT) v The Registrar General for England and Wales [2019] EWHC 2384 (Fam).
11. Human Fertilisation and Embryology Act 1990
12. Gender Recognition Act 2004.
13. A. Shetty, Y. Dong, J. Goldman, M. Akiska, B. Ranganath, Uterine Transplantation in Transgender Individuals as Gender Affirma-

tion Surgery, George Washington University School of Medicine and Health Sciences, Washington DC, 2023: 1.
14. B. Bruno, K. Shah Arora, Uterus Transplantation: The Ethics of Using Deceased Versus Living Donors, American Journal of Bioethics, Volume 18, Issue 7, 2018: 7.
15. Lavoué, V., C. Vigneau, S. Duros, K. Boudjema, J. Levêque, P. Piver, Y. Aubard, T. Gauthier., Which donors for uterus transplants: Brain-dead donor or living donor? A systematic review, Transplantation 101(2), 2017: 271.
16. Swedish National Council on Medical Ethics, (SMER) S1985:A/2016/00675 2016-09-26.
17. R. Tonkens, Gatekeeping uterus transplants: a proposal for eligibility criteria and the fair allocation of wombs, International Legal and Ethical Perspectives on Uterus Transplantation, Edward Elgar Publishing Limited, London, 2024: 140-142.
18. MJ. Bayefsky, E. Berkman, The Ethics of Allocating Uterine Transplants, Cambridge Quarterly of Healthcare Ethics, Cambridge University Press, Cambridge, 2016: 353-361.
19. M. Akan, Transplant health inequities research from an operations perspective, Health Sciences Review 11, 100176, Tepper School of Business, Carnegie Mellon University, USA, 2024: 1.
20. JMJJ. Mavuso, Repronormativity in cisgender men's reasons why they would not use womb transplant technology to become pregnant, Sociology Compass, Volume 17, Issue 2, e13054, Sociology Department, University of Pretoria, Lynwood, South Africa, 2022: 11-13.
21. G. Barn, A right to gestate? Uterus transplants and the language of rights, International Legal and Ethical Perspectives on Uterus Transplantation, Edward Elgar Publishing Limited, London, 2024: 61-72.
22. R. Chmel, Z. Pastor, J. Matecha, L. Janousek, M. Novackova, J. Fronek, Uterine transplantation in an era of successful childbirths from living and deceased donor uteri: Current challenges, Biomedical Papers, Medical Faculty University of Palacky Olomouc, Czech Republic, 2020: 116.
23. M. Lotz, Uterus transplantation and adoption in the empirical and normative context: the question of alternative parenthood modalities, International Legal and Ethical Perspectives on Uterus Transplantation, Edward Elgar Publishing Limited, London, 2024: 54.

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ISSN: 2653-8660